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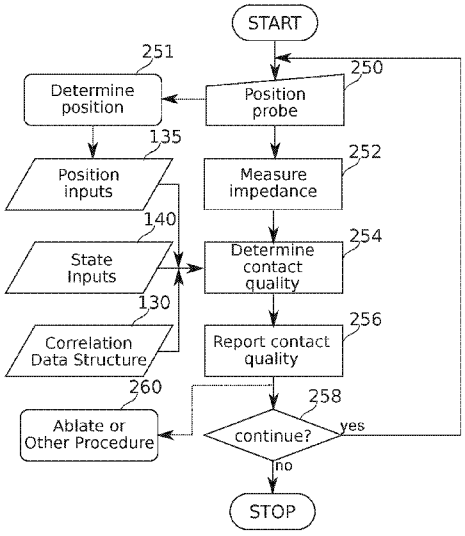

FIG. 2

(57) Abstract: Devices and methods for assessing tissue contact based on dielectric properties and/or impedance sensing are disclosed. In some embodiments, one or more probing frequencies are delivered via electrodes including an electrode in proximity to a tissue (for example, myocardial tissue). In some embodiments, dielectric parameter values, optionally together with other known and/or estimated tissue characteristics, are measured to determine a contact quality with the tissue. In some embodiments, dielectric contact quality is used, for example, in guiding the formation of a lesion (for example, RF ablation of heart tissue to alter electrical transmission characteristics).

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CONTACT QUALITY ASSESSMENT BY DIELECTRIC PROPERTY ANALYSIS

RELATED APPLICATIONS

This application claims the benefit of priority under 35 USC §119(e) of U.S. Provisional Patent Application No. 62/160,080 filed May 12, 2015; U.S. Provisional Patent Application No. 62/291,065 filed February 4, 2016; and U.S. Provisional Patent Application No. 62/304,455 filed March 7, 2016; the contents of which are incorporated herein by reference in their entirety.

This application is co-filed with International Patent Applications having Attorney Docket Nos.: 66011 SYSTEMS AND METHODS FOR TRACKING AN INTRABODY CATHETER, 66142 CALCULATION OF AN ABLATION PLAN, 64488 FIDUCIAL MARKING FOR IMAGE-ELECTROMAGNETIC FIELD REGISTRATION, and 66012 LESION ASSESSMENT BY DIELECTRIC PROPERTY ANALYSIS, the contents of which are incorporated herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to systems and methods for probe positioning within a body cavity, and more particularly, but not exclusively, assessment of contact between an intra-body electrode and a body cavity surface.

RF ablation probes are in use for minimally invasive ablation procedures, for example, in the treatment of cardiac arrhythmia. A high frequency alternating current (*e.g.*, 350-500 kHz) is introduced to a treatment region through the probe, creating an electrical circuit involving tissue, which heats up as it absorbs energy of the applied electrical field. The heating results in effects such as tissue ablation. In the control of cardiac arrhythmia, a goal of ablation is to create lesions in a pattern which will break pathways of abnormal electrophysiological conduction which contribute to heart dysfunction (such as atrial fibrillation).

One variable affecting the heating is the frequency-dependent relative permittivity κ of the tissue being treated. The (unitless) relative permittivity of a material (herein, κ or dielectric constant) is a measure of how the material acts to reduce an electrical field imposed across it (storing and/or dissipating its energy). Relative

permittivity is commonly expressed as $\kappa = \varepsilon_r(\omega) = \frac{\varepsilon(\omega)}{\varepsilon_0}$, where $\omega = 2\pi f$, and f is the frequency (of an imposed voltage or signal). In general, $\varepsilon_r(\omega)$ is complex valued; that is: $\varepsilon_r(\omega) = \varepsilon'_r(\omega) + i\varepsilon''_r(\omega)$.

The real part $\varepsilon'_r(\omega)$ is a measure of energy stored in the material (at a given electrical field frequency and voltage), while the imaginary part $\varepsilon''_r(\omega)$ is a measure of energy dissipated. It is this dissipated energy that is converted, for example, into heat for ablation. Loss in turn is optionally expressed as a sum of dielectric loss ε''_{rd} and conductivity σ as $\varepsilon''_r(\omega) = \varepsilon''_{rd} + \frac{\sigma}{\omega \cdot \varepsilon_0}$.

Any one of the above parameters: namely κ, ε, ε'_r, ε''_r, σ, and/or ε''_{rd}, may be referred to herein as a dielectric parameter. The term dielectric parameter encompasses also parameters that are directly derivable from the above-mentioned parameters, for example, loss tangent, expressed as $\tan\sigma = \frac{\varepsilon''_r}{\varepsilon'_r}$, complex refractive index, expressed as $n = \sqrt{\varepsilon_r}$, and impedance, expressed as $Z(\omega) = \sqrt{\frac{i\omega}{\sigma + i\omega\varepsilon_r}}$ (with $i = \sqrt{-1}$).

Herein, a *value of a dielectric parameter* of a material may be referred to as a *dielectric property* of the material. For example, having a relative permittivity of about 100000 is a dielectric property of a 0.01M KCl solution in water at a frequency of 1 kHz, at about room temperature (20°, for example). Optionally, a dielectric property more specifically comprises a measured value of a dielectric parameter. Measured values of dielectric parameters are optionally provided relative to the characteristics (bias and/or jitter, for example) of a particular measurement circuit or system. Values provided by measurements should be understood to comprise dielectric properties, even if influenced by one or more sources of experimental error. The formulation "value of a dielectric parameter" is optionally used, for example, when a dielectric parameter is not necessarily associated with a definite material (*e.g.*, it is a parameter that takes on a value within a data structure).

Dielectric properties as a function of frequency have been compiled for many tissues, for example, C. Gabriel and S. Gabriel: *Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies* (web pages presently maintained at www://niremf(dot)ifac(dot)cnr(dot)it/docs/DIELECTRIC/home(dot)html).

Dielectric properties comprise certain measured and/or inferred electrical properties of a material relating to the material's dielectric permittivity. Such electrical properties optionally include, for example, conductivity, impedance, resistivity, capacitance, inductance, and/or relative permittivity. Optionally, dielectric properties of a material are measured and/or inferred relative to the influence of the material on signals measured from electrical circuits. Optionally, dielectric properties of a material are measured and/or inferred relative to the influence of the material on an applied electric field. Measurements are optionally relative to one or more particular circuits, circuit components, frequencies and/or currents.

Microscopically, several mechanisms potentially contribute to electrically measured dielectric properties. For example, in the kHz-MHz range, movement of ionic charge carriers generally dominates. In many tissues, cellular membranes play a significant role in the compartmentalization of ionic charges. Conductance pathways are also potentially influenced by the cellular structure of a tissue. Dielectric properties optionally are influenced by and/or take into account non-dielectric properties such as temperature.

SUMMARY OF THE INVENTION

There is provided, in accordance with some exemplary embodiments, a method of characterizing contact quality of an intra-body probe with a target tissue, comprising: measuring dielectric properties of the environment of an electrode of an intra-body type electrode using an electrical circuit, the electrical circuit being defined by the electrode placed intra-bodily so that the target tissue is included in the electrical circuit; and characterizing contact between the probe and the target tissue, wherein the characterization of the contact comprises mapping of the measured dielectric properties to a mapped value within a range of values characterizing the contact quality.

According to some embodiments, the mapped value comprises an index characterizing contact quality.

According to some embodiments, the mapped value represents a contact force equivalent, such that a force of contact of the intra-body probe with the target tissue is represented by the mapped value.

According to some embodiments, the range of values characterizing the contact quality comprises at least four possible values.

According to some embodiments, the intra-body probe comprises an ablation electrode configured for ablation of the target tissue.

According to some embodiments, the ablation electrode comprises the electrode defining the electrical circuit.

According to some embodiments, the characterizing comprises evaluating sufficiency of the contact for effective lesioning by the ablation electrode.

According to some embodiments, the method comprises providing a user feedback indicating the sufficiency of contact for effective lesioning.

According to some embodiments, the ablation electrode is configured for the formation of a lesion in the target tissue by at least one of the group consisting of: thermal ablation, cryoablation, RF ablation, electroporating ablation, and/or ultrasound ablation.

According to some embodiments, the method comprises operating an ablation electrode based on the characterization of the contact.

According to some embodiments, the operating of the ablation electrode is gated to occur only when the characterized contact is within a predetermined range.

According to some embodiments, the characterizing contact is performed iteratively during operating of the ablation electrode.

According to some embodiments, the operating of the ablation electrode is based on an estimated contact force of the characterized contact, such that at least one of an ablation power, a duration of ablation, a selection of an electrode, and a frequency of ablation energy, is selected based on the estimated contact force.

According to some embodiments, the characterizing comprises estimation of an equivalent force of contact of the probe with a surface of the target tissue.

According to some embodiments, the estimation of an equivalent force of contact is substantially independent of an angle of contact between the probe and the surface of the target tissue.

According to some embodiments, the characterizing comprises evaluating a risk of perforation of the target tissue by the probe.

According to some embodiments, the method comprises providing a user feedback indicating the risk of perforation.

According to some embodiments, the method comprises moving the probe under automated control based on the characterization of the contact.

According to some embodiments, the target tissue comprises cardiac tissue.

According to some embodiments, the target tissue comprises cardiac tissue of the right atrium.

According to some embodiments, the intra-body probe makes a plurality of simultaneous contacts with the target tissue, and the characterizing comprises separately characterizing each of the plurality of simultaneous contacts.

According to some embodiments, the intra-body probe comprises an ablation electrode, and wherein the method comprises operating the ablation electrode to ablate at each of the plurality of simultaneous contacts under separate control, based on the corresponding characterizing of contact.

According to some embodiments, the separate control comprises delivery of a separately selected at least one of a frequency, phase, or level of ablation power to each of the plurality of simultaneous contacts.

According to some embodiments, the separate control comprises separately selected timing of delivery of ablation power to each of the plurality of simultaneous contacts.

According to some embodiments, the characterizing of contact is based on a data structure mapping measured dielectric properties to a characterization of contact with the target tissue.

According to some embodiments, the character of contact comprises at least one from among the group consisting of: a risk of perforating the tissue with the intra-body probe, an estimate of contact force applied to the tissue by the intra-body probe, and/or an assessment of adequate contact for reliable ablation using the intra-body probe.

According to some embodiments, the data structure comprises machine-learned associations applicable to the measured dielectric properties to convert them to the characterization of contact with the target tissue.

According to some embodiments, the dielectric properties comprise dielectric properties measured for a plurality of electrical field frequencies.

According to some embodiments, the electrical field frequencies are in a range between about 5 kHz and about 20 kHz.

There is provided, in accordance with some exemplary embodiments, a device for ablation of a target tissue based on dielectric contact quality of an intra-body ablation probe with the target tissue, comprising: the intra-body ablation probe, including at least one electrode; an electrical field measurement device, configured to measure dielectric properties in the environment of the at least one electrode based on signals sensed by the at least one electrode; and a contact characterization module, configured to characterize contact between the intra-body ablation probe and the target tissue, based on the dielectric properties measured by the electrical field measurement device.

According to some embodiments, the contact characterization module comprises a data structure mapping the dielectric properties to characterization of contact.

According to some embodiments, the device comprises a display configured to display the characterized contact as an estimate of contact force.

There is provided, in accordance with some exemplary embodiments, a method of indicating the orientation of a displayed view of an anatomical structure, comprising: displaying on a display an anatomical view of the anatomical structure in a user-adjustable orientation; and coordinating an orientation of a displayed schematic representation of a portion of the anatomical structure to the user-adjustable orientation of the anatomical view, such that the schematic representation is displayed in the same orientation as the anatomical view of the anatomical structure; wherein the schematic representation comprises a body portion representing a first part of the anatomical structure, and a plurality of protruding portions representing protruding portions of the anatomical structure and protruding from the body portion, such that the orientation of the plurality of protruding portions is identifiable from any orientation of the displayed schematic representation.

According to some embodiments, the anatomical structure comprises an atrium of a heart.

According to some embodiments, the body portion of the schematic representation comprises at least two sub-portions; each sub-portion being distinctively shaded, and corresponding to a predetermined portion of the anatomical structure.

According to some embodiments, the anatomical view of the anatomical structure includes a view of at least one obscuring anatomical portion positioned to obscure the predetermined portions of the anatomical structure, and wherein the schematic representation omits to represent this obscuring anatomical portion, thereby preventing obscuring of the at least two portions of the schematic representation.

According to some embodiments, each of the at least two sub-portions of the schematic representation corresponds to an atrium of a heart, and the plurality of protruding portions comprise a plurality of generally cylindrical protrusions corresponding to the number of veins feeding into each atrium.

According to some embodiments, the plurality of protruding portions comprise a protrusion indicating a position of a heart valve.

There is provided, in accordance with some exemplary embodiments, a method of characterizing contact quality of an intra-body probe with a target tissue, comprising: measuring dielectric properties of the environment of an electrode of an intra-body type electrode using an electrical circuit, the electrical circuit being defined by the electrode placed intra-bodily so that the target tissue is included in the electrical circuit; and characterizing contact between the probe and the target tissue, wherein the characterization of the contact comprises conversion of the measured dielectric properties to an equivalent contact force estimation, and wherein the estimation of an equivalent force of contact is substantially independent to an angle of contact between the probe and the surface of the target tissue.

According to some embodiments, the substantial independence comprises a change of less than 10% through a range of angles of contact, and the range of angles of contact is within 45° of a central angle of contact.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

As will be appreciated by one skilled in the art, aspects of the present invention may be embodied as a system, method or computer program product. Accordingly, aspects of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, micro-code, *etc.*) or an embodiment combining software and hardware aspects that may all generally be referred to herein as a "circuit", "module" or "system". Furthermore, some embodiments of the present invention may take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the invention can involve performing and/or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, *e.g.*, using an operating system.

For example, hardware for performing selected tasks according to some embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to some exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the invention. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-

exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electro-magnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for some embodiments of the present invention may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the “C” programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to

an external computer (for example, through the Internet using an Internet Service Provider).

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example, and for purposes of illustrative discussion of embodiments of the invention. In this regard,

the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIG. 1A schematically represents a catheter probe being brought into contact with a tissue wall for measurement of a dielectric contact quality therebetween, according to some embodiments of the present disclosure;

FIG. 1B is a simplified and schematic plot of contact force and dielectric contact quality as a function of advancement of probe against tissue wall, according to some embodiments of the present disclosure;

FIG. 1C is a simplified and schematic plot of contact force and dielectric contact quality as a function of time and advancement of probe against a cyclically moving tissue wall, according to some embodiments of the present disclosure;

FIG. 1D schematically represents rotation of a catheter probe through a range of contact angles with a tissue wall for measurement of a dielectric contact quality therebetween, according to some embodiments of the present disclosure;

FIG. 1E schematically represents a catheter probe comprising a contact force sensor, according to some embodiments of the present disclosure;

FIG. 1F is a simplified and schematic plot of contact force and dielectric contact quality as a function of time and angle of probe against a cyclically moving tissue wall, according to some embodiments of the present disclosure;

FIG. 1G schematically illustrates a system for the measurement of tissue dielectric properties, according to some embodiments of the present disclosure;

FIG. 2 is a flowchart of a method for the measurement of tissue dielectric properties for determination of contact quality, according to some embodiments of the present disclosure;

FIG. 3 schematically illustrates a catheter-deployed probe comprising a plurality of electrodes configured for sensing of dielectric contact quality, according to some embodiments of the present disclosure;

FIG. 4 illustrates a graphical user interface (GUI) widget for display of dielectric contact quality information to a user, according to some embodiments of the present disclosure;

FIG. 5 is a graph presenting estimates of contact force derived from dielectric contact quality measurements, the estimated contact forces being plotted with respect to directly sensed contact forces, according to some embodiments of the present disclosure;

FIG. 6 is a graph of receiver operating characteristic (ROC) presenting for the data of FIG. 5 a true positive rate versus false positive rate for dielectric contact quality-based estimation of contact force above a threshold of grams-force, according to some embodiments of the present disclosure;

FIG. 7A schematically illustrates a view of a graphical user interface (GUI) widget, representative of the-D orientation of the atria of a heart in space, according to some embodiments of the present disclosure;

FIG. 7B schematically illustrates a heart in an orientation corresponding to the orientation of GUI widget, according to some embodiments of the present disclosure;

FIG. 7C shows views of six different orientations of GUI widget, separated by about° from each other, according to some embodiments of the present disclosure;

FIG. 7D shows the views of FIG. 7C reduced in size, alongside corresponding anatomical views of a heart, according to some embodiments of the present disclosure;

FIGs. 8A-8E illustrate a display for indicating lesioning status, including contact force, to a user, according to some exemplary embodiments;

FIG. 9 illustrates display elements which are optionally used to indicate estimated transmurality of a lesion to a user, based on pre- and post- lesioning dielectric property measurements;

FIG. 10 is a graph presenting dielectric property-estimated contact force vs. directly measured force, according to some exemplary embodiments of the invention.

FIG. 11A graphs contact force measurements using a force sensing catheter;

FIG. 11B graphs contact quality level estimates made based on dielectric measurements for the epoch also shown in *Figure 11A*;

FIG. 11C graphs contact force measurements using a force sensing catheter; and

FIG. 11D graphs contact quality level estimates made based on dielectric measurements for the epoch also shown in *Figure 11C*.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to systems and methods for probe positioning within a body cavity, and more particularly, but not exclusively, assessment of contact between an intra-body electrode and a body cavity surface.

Overview

An aspect of some embodiments of the present invention relates to evaluation of contact between an electrode and a tissue surface based on multi-parameter dielectric property measurements. In some embodiments, the electrode is intra-body (for example, an electrode introduced into the body over a catheter), and the tissue surface is an internal surface, for example, the wall of a heart, or of another organ such as a lumen of the digestive tract (*e.g.*, the stomach).

In some embodiments, dielectric property measurements include sampling of electrical signals affected by dielectric properties in the environment surrounding the intra-body electrode. Movement of the intra-body electrode, and in particular, movement that affects a degree of contact with an internal surface of a target tissue, changes this environment, leading to changes in measured dielectric properties. In some embodiments, the evaluated contact is converted to and/or expressed as a dielectric contact quality, for example as a value from along a dielectric contact quality scale.

For certain applications comprising transcatheter delivery of a disease treatment, it is a potential advantage to distinguish between different degrees of contact between a probe which delivers the treatment, and tissue being treated. Degree of contact potentially affects treatment results; for example, by affecting the coupling of energy transfer between a treatment probe and target tissue. For embodiments in which a treatment relies on energy transfer (heating or cooling, for example) "contact quality *per se*" refers to how the various physical correlates of degree of contact (*e.g.*, contact surface area and/or microscopic distances between surfaces approaching one another) influence such coupling. Actual measures of parameters affected by contact, including, for example, contact force and dielectric contact quality, may in turn be understood as measures of contact quality which estimate contact quality *per se*, and thus also, for example, are optionally used as predictors of a probe-delivered procedure's effectiveness.

In some embodiments of the invention, electromagnetic signals indicative of dielectric properties of an electrode's environment are converted into one or more measures of contact quality. In some embodiments, the conversion comprises a mapping from measurements of a plurality of dielectric properties to a mapped value. Herein, such a dielectric property-derived measure of contact quality is referred to as a measure of "dielectric contact quality" (that is, a contact quality which is dielectrically derived). Optionally, dielectric properties are determined by analysis of multidimensional signals (e.g. indicative of impedance characteristics of tissue nearby (including contacting) a sensing electrode. The signals carry information indicative, for example, of imaginary and/or real components of impedance as a function of a plurality of electrical field frequencies.

Optionally, these multidimensional signals are converted to a simpler (e.g., lower-dimensional, for example, single-dimensional) representation as a value on a scale of dielectric contact quality. In some embodiments, dielectric contact quality is expressed as a category expressing a character of contact (sufficient, insufficient, and/or excessive contact, for example), and/or as a numerical value which characterizes contact, the characterizing value being with or without units (*e.g.*, 20%, 10 grams-force, a scale of integers, *etc.*). In some embodiments, at least four different levels of dielectric contact quality are identified. Optionally, at least two levels of sufficient contact (sufficient for performance of an ablation or other procedure, for example) are distinguished. In some current practice, contact force (as measured, for example, by a piezoelectric force sensor) is used as a standard for estimating a contact quality *per se*. In some embodiments of the present invention, a quality of contact is expressed as a contact force equivalent. For example, a certain contact quality is optionally expressed in units of gram-force which correlate with units of gram-force actually exerted by the contact, even though the actual measurement is optionally by the analysis of signals which are not of contact force.

Use of contact force measured by an ablation probe force sensor has been introduced in the prior art for ablation treatment (by RF ablation, for example) of atrial fibrillation (AF). Ablation performed in this treatment approach seeks to abolish atrial fibrillation by cutting (at the point of ablation) conduction pathways leading between regions of impulse initiation and contractile myocardial tissue. For example, ablation is

optionally performed to cut off sites of electrical impulse generation in or near the pulmonary veins (PV) from the rest of the heart.

AF can recur, for example, in about 50% of patients after ablation, with the majority of recurrences (about 95%, for example) being associated with the restoration of a conductive pathway leading from a pulmonary vein (PV reconnection). Use of contact force measurement to guide ablation has led to an apparent reduction in PV reconnection. Nevertheless, it has been observed that the efficacies of some alternative 'cut and sew' (Cox-MAZE) methods of interrupting conduction pathways continue to exceed that of catheter-based AF ablation, even using contact force as a guide. Moreover, current methods of contact force measurement rely on specialized probes comprising a force sensor.

Dielectric contact quality offers some potential advantages over contact force as an estimator of contact quality *per se*. For example, the impedance of an electrical circuit comprising tissue near the contact between the probe and the tissue may be indicative of electromagnetic coupling affecting the transfer of ablation energy between a probe and tissue. As a measure of electromagnetic coupling, contact force measurement is potentially a more indirect indication than dielectric contact quality. Also for example, it is a potential advantage for directness of measurement to use the same electrode for both contact sensing and ablation (this is possible, for example, when using RF ablation). Furthermore, it is a potential advantage to be able to obtain a measure of contact quality using a probe that lacks a special additional force sensor. In some embodiments, a multi-electrode probe is provided; *e.g.*, a probe comprising a plurality of electrodes arranged along a longitudinal extent of the probe. Optionally, the electrodes are arranged on the probe (for example, the probe may be flexible) so that they can be brought into simultaneous contact with a tissue surface. In some embodiments, each of the plurality of electrodes is separately operable for determination of a corresponding dielectric contact quality. This is a potential advantage for multi-electrode applications, since it may be prohibitively difficult to provide each electrode with its own corresponding force sensor.

An aspect of some embodiments of the present invention relates to the representation of dielectrically measured contact quality between an electrode and a tissue surface as a force-unit equivalent. In some embodiments, a displayed indication

of dielectric contact quality is presented to a user as an estimated equivalent value in units of force. This is a potential advantage for allowing dielectric contact quality results to be referenced to a device-independent standard. For example, tissue contact guidelines in a protocol for treatment (*e.g.*, tissue ablation) are optionally provided in terms of a unit of force such as grams-force, Newtons, millinewtons, or another standard unit.

In some embodiments, a calibration scale allowing the translation form dielectric contact quality to contact force is obtained from training trials in which contact force is directly observed in conjunction with dielectric contact quality measurement.

In some embodiments, a display of dielectric contact quality comprises two or more complementary displays; for example, a graphical bar display allowing at-a-glance (optionally, peripherally viewed) judgment of general contact status, together with one or more numeric indications suitable to direct comparison with protocol guidelines.

An aspect of some embodiments of the present disclosure relates to the use of a graphical user interface (GUI) widget for representation of an organ orientation in a 3-D space. In some embodiments, the organ is a heart, or portion of heart anatomy, for example, atria of a heart.

In some embodiments, a mutable 3-D view of an organ's anatomy is presented to a user for use in tasks such as procedure planning, probe navigation and/or probe positioning. The 3-D view is optionally mutable in one or more of a numerous respects including not only orientation, but also (for example) color, completeness, texture, transparency, and/or scale. This mutability provides a potential advantage for rich visual presentation of information. For example, regions of interest can be magnified for detailed work; color mappings are optionally used to represent physiological parameters such as tissue vitality and/or thickness. However, mutable display also creates a risk of cognitive overload which potentially leads to operator disorientation, distraction, and/or fatigue. A sense of spatial orientation in particular can be difficult to continually maintain, yet awareness of orientation is potentially crucial to the success of a procedure comprising navigation of a catheter probe through complex and/or constraining anatomical structures.

In some embodiments, a GUI widget representative of the features of an organ is provided for coordinated display with a 3-D view of an organ's anatomy. The

coordination, in some embodiments, comprises coordinated adjustment of the orientation of the GUI widget to the orientation of the anatomical view, such that knowing the orientation of the GUI widget uniquely determines the 3-D orientation of the anatomical view. The GUI widget is optionally manipulated by user input directed at the GUI widget itself, and/or updated to reflect user input directed at another control (for example, sliders, buttons, and/or the anatomical view display itself).

Optionally, the GUI widget is comprised of simple geometrical shapes which suggest (without literally depicting) anatomical landmarks of the true anatomy. Optionally, the landmarks which are shown are those most salient to treatment and/or diagnostic activities that the anatomical display is supporting. For example, blood vessels which mark navigation pathways and/or treatment zones are optionally shown as cylindrical tubes. Complex shapes (such as the atria and valves) are optionally reduced to a small number of salient visual indications, such as position and/or relative size. GUI widget representation of anatomical structures peripheral to an operator's activities (for example, the ventricles) are optionally suppressed altogether. Such a GUI widget provides a potential advantage in striking a balance between two opposing constraints: being visually stable and simple enough that orientation is instantly identifiable to a device operator, yet being enough similar to actual anatomy that orientation homology is directly apparent.

Optionally, one or more indications of anatomical structures separate from the displayed anatomy are provided for indication of orientation. For example, a cylinder showing the relative position of the esophagus (which can potentially be at risk for damage during ablation) is optionally displayed near a schematic model of the atria. In some embodiments, a portion of a lumen of the digestive tract (*e.g.*, a stomach) is schematically represented. Optionally, orientation is indicated by cylinders representing entrance and exit passages from the represented tissue. Optionally, orientation is indicated by a schematic representation of the position of a characteristic bend of a lumenal structure, for example: a bend of a large intestine or an arch of an aorta.

In some embodiments, a GUI widget is adjustable in one or more characteristics additional to orientation. For example, view scale is optionally indicated by marking of anatomical view regions on the GUI widget. Optionally, internal anatomy views (as is from within an atrium for example) are distinguished from external anatomy views.

This is performed, for example, by visually cutting away a portion of the GUI widget so that its modeled interior is seen.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Dielectric Contact Quality

Reference is now made to FIG. 1A, which schematically represents a catheter probe **111** being brought into contact with a tissue wall **50** for measurement of a dielectric contact quality therebetween, according to some embodiments of the present disclosure. Reference is also made to FIG. 3, which schematically illustrates a catheter-deployed multi-electrode probe **112** comprising a plurality of electrodes **103** configured for sensing of dielectric contact quality, according to some exemplary embodiments of the present disclosure.

In some embodiments, at least one electrode **103** of a catheter probe **111**, **112** is configured for use in producing a time-varying electrical field **104** across tissue wall **50** (a second electrode used in field production not shown), while the probe **111**, **112** approaches and is forced into contact with a tissue contact region **106**. In some embodiments, each individual electrode **103** of multi-electrode probe **112** optionally separately defines a tissue contact region **106**. Electrodes **103** of multi-electrode probe **112** are optionally operated to produce an electrical field between pairs of electrodes **103**, and/or between an electrode **103** and an electrode positioned remotely. Electrode **103** is also configured for the measurement of signals from the time-varying electrical field **104** which reflect the dielectric properties of the electrode's environment. In some embodiments, these signals change as the probe **111** is moved through a distance **61**, for example, from position **111A** to position **111B**. In particular, signals received potentially change significantly during movement between an initial contact of probe **111** with tissue contact region **106**, and a later contact wherein probe **111** has been further forced against tissue contact region **106**.

Herein, tissue ablation from a probe provides an example of a probe-delivered, contact quality-dependent procedure. It is to be understood that other probe contact

quality-dependent procedures are also included within the scope of this disclosure; for example, contact as a preliminary to biopsy sampling.

In some embodiments, probe **111** (optionally electrode **103** itself) is adapted for use to ablate tissue at contact region **106**. The outcome of such ablation, and in particular RF ablation, has been found to significantly depend on how contact is formed between the ablation probe and the tissue. Optionally, for example, a degree of contact coupling between an ablation probe and target tissue affects how energy is transferred between them to produce ablation. Dielectric assessment of contact also provides a potential advantage in evaluation of data applicable to other dielectric measurement modalities. For example, the validity of dielectric tissue state assessment (*e.g.*, lesion extent and/or continuity, tissue edema) is optionally verified at least in part by confirmation of a minimum quality of contact by the electrode used for measurement.

In some embodiments, other electrodes, another catheter probe and/or another ablation method is used in a procedure, for example, cryoablation, ultrasound ablation, laser ablation, electroporating ablation, or another form of ablation. In such instances, coupling of contact quality sensed by electrode **103** to effective contact by the portion of the probe comprising an element which is actuated to perform a treatment procedure is optionally obtained, for example, by putting both electrode **103** and the treatment element on the same probe. Optionally, the contact sensing electrode and the procedure administrating portion (*e.g.*, lesioning element) of the probe are positioned, for example, alongside each other, encircling one another, and/or interpenetrating one another at a contact surface. Additionally or alternatively, a contact offset between the two probe elements is accounted for in calibration. In some embodiments, a plurality of probes (*e.g.*, one carrying the contact sensing electrode, and one carrying the procedure administrating portion) are positioned in tandem so that a sensed dielectric contact quality from a first probe provides useful information about the contact quality of a second probe.

In some embodiments, a plurality of electrodes **103** on a multi-electrode probe **112** used in sensing of dielectric contact quality are optionally operable for treatment (*e.g.*, lesioning) and/or assessment of treatment result (dielectric assessment of treatment results, e.g., lesion characteristics, is described, for example, in U.S Provisional Patent Application No. 62/291,065 to the applicant, the contents of which

are incorporated herein by reference in their entirety. For example, probe **112** is optionally flexible (*e.g.*, into a loop shape as shown in FIG. 3) to assume the shape of a portion of an extended train of tissue lesion foci, allowing electrodes **103** to be positioned therealong. Assessment of contact quality for each electrode provides a potential advantage by allowing the selective operation of electrodes in good contact for ablation and/or dielectric tissue assessment, reducing the potential for ineffective treatment and/or spurious results due to lack of quality contact at one or more of the electrode positions.

In some embodiments, evaluation of contact quality comprises categorization of contact quality. For example, a distinction is made between contact which is sufficient for successful ablation, and contact which is insufficient. In some embodiments, contact force large enough to create a potential risk of tissue perforation is distinguished as another category. Optionally, contact quality comprises a quantitative evaluation; for example, ordered (optionally, continuous) gradations between and/or within each category of contact.

In some embodiments of the invention, signals and/or their changes indicative of dielectric properties of the environment of electrode **103** are converted into one or more measures of contact quality. The conversion optionally involves dimensional reduction of the inputs from which contact quality is derived.

For example, impedance measurements used as inputs of this conversion are optionally multidimensional (impedance measurements are used, in some embodiments, as indications of dielectric properties). An impedance measurement may comprise an impedance value for each of a plurality of frequencies. Each impedance value may have a real part and/or an imaginary part, which may be considered a dimension of the input.

Parameters that affect signals indicative of dielectric properties may include, for example, not only contact quality, but also aspects of other elements of the contact quality measurement circuit, for example:

- The configuration of circuit elements including the probe **111** and/or electrode **103** itself;
- The dielectric properties of tissue including tissue wall **50**, tissue contact region **106**, and/or other tissue (such as body tissue **102** of FIG. 1G) in which electrical field **104** is established; and

- The configuration of other circuit elements, for example, skin patches **105** (FIG. 1G), leads, and other electrical components of a dielectric measurement system.

Nevertheless, the inventors have surprisingly found it possible to determine a correspondence (by correlation, for example) between multidimensional dielectric measurements and one or more other measures of contact quality. Insofar as force-measuring probes are currently available and in use, contact force measurement provides a preferred example of a reference against which calibration of dielectric contact quality is optionally performed. However, estimation of contact quality based on dielectric measurements is not limited to comparisons with contact force measurements. For example, results of dielectric measurements may be correlated with (or calibrated against) direct measurements of procedure results (*e.g.*, ablation effectiveness). Optionally, a measure of contact quality comprises a combined assessment of dielectric contact quality and contact force as measured by a force-sensing probe. For example, optionally, an anticipated procedure result is jointly predicted by sensed force and dielectric contact quality.

In some embodiments of the current invention, there is a correspondence determined between dielectric measurements, and the force with which a probe **111** bearing an electrode **103** is pushed into a tissue contact region **106**. Herein, such a determined correspondence is called a scale of dielectric contact quality. Contact force can be directly measured, for example, from the deformation of a piezoelectric device mounted to a specialized force-measuring catheter probe.

Optionally, correspondence is determined by means of a calibration procedure. The calibration procedure comprises, for example, simultaneously measuring both dielectric properties and contact forces in a number of calibration experiments (for example, 100, 1000, 10000, or another larger or intermediate number of calibration experiments). Optionally, calibration experiments are performed with an *ex vivo* preparation of the target tissue of interest; for example, a preparation of myocardial tissue when dielectric contact quality with heart wall tissue is to be determined. Additionally or alternatively, calibration comprises measuring dielectric properties from a probe during a procedure and corresponding experimental and/or actual procedure results (for example, ablation lesion results). From these data, a dielectric contact quality scale is determined in some embodiments; for example, by use of statistical

analysis, machine learning, and/or another technique for extracting associations from multivariate data. In some embodiments, further information is used; for example, anatomical data (*e.g.*, general atlas data, and/or data personalized to the patient) and/or probe position data. Optionally, this further information serves to affect how a scale is applied, for example, by providing values of parameters affecting dielectric contact quality determination. Optionally, relationships established by the calibration procedure are provided as data structure **130** of a contact quality assessing system **100**, for example, as described in relation to FIG. 1G. Optionally, data structure **130** comprises a mapping between a plurality of dielectric measurement results, and a corresponding plurality of values along a contact quality scale. The contact quality scale is optionally one dimensional. Optionally the scale is expressed in units equivalent to force. Additionally or alternatively, it is expressed in terms of an arbitrary unit (for example, a one or two digit value on a relative scale).

In some embodiments, a contact quality assessing system **100** includes calibration data (for example, data structure **130**) for a plurality of different probe **111** and/or electrode **103** types. The calibration data for use is optionally selected based upon identification of the probe **111** and/or electrode **103** type. In some embodiments a probe **111** and/or electrode **103** is provided together with calibration data (for example, data structure **130**) which can be in turn provided to contact quality assessing system **100** for use. Optionally, the calibration data is individualized to the provided probe **111** and/or electrode **103**. In some embodiments, a calibration phantom is provided which allows at least partial recalibration of probe **111** and/or contact electrode **103**. For example, the calibration phantom optionally comprises a mount for probe **111**, and a force sensor which measures the force with which electrode **103** presses against a phantom tissue which is part of the calibration phantom (for example, a fluid-filled bag, a polymer membrane, and/or another artificial substitute for contacted tissue). Optionally, force and/or dielectric property measurements made using the calibration phantom are used as indications to adjust use of data structure **130** so that contact quality assessments are calibrated for the particular configuration of the contact quality assessing system **100**.

Reference is now made to FIG. 1B, which is a simplified and schematic plot of contact force and dielectric contact quality as a function of advancement of probe **111** against tissue wall **50**, according to some embodiments of the present disclosure.

Arrow **61** represents the motion **61** of FIG. 1A. Dotted line **65A** represents a direct force generated between the probe **111** and the tissue contact region **106**. Initially (*e.g.*, up to inflection point **65B**), this force is substantially zero. It begins to rise on initial contact, and continues to rise until the end of the graph. The rise of force as a function of distance is simplified to a linear relationship for purposes of illustration. Also in the example of FIG. 1B, and during the same advancement of probe **111** into tissue, dielectric measurements are optionally taken. Solid line **66A** represents the evolution of a measure of contact quality which these dielectric measurements comprise (the conversion being performed, for example, as determined by a previous calibration procedure).

While the two measures (*e.g.*, of direct contact force and of dielectric contact quality) are not necessarily linearly related throughout the calibration range, there are, in some embodiments, three regions in particular which can be assigned a qualitative functional significance. Region **62** of FIG. 1B is a low-contact region of the graph, optionally defined as a region of the graph within which there is an elevated risk of failure for a procedure (an ablation procedure, for example) performed at that level of contact. Region **64** is an excessive-contact region of the graph, optionally defined as a region of the graph within which there is an elevated risk of perforation by probe **111**, and/or other mechanical trauma. Region **63** represents an intermediate region of contact quality within which procedure success (ablation procedure success, for example) is predicted.

As represented, the relationship between contact force and contact quality is approximately linear in the predicted success range **63** (a non-linear relationship is also possible). Optionally, there are larger deviations from linearity in range **64** and/or range **62**. This is shown also in the data-derived example of actual vs. estimated contact force of FIG. 5. The deviation (apparent loss of sensitivity, for example) is not necessarily a practical limitation of the dielectric method: the extreme ranges anyway are optionally considered as “avoided regions” for purposes of treatment. Moreover, it should be understood that contact force, though optionally used as a reference standard (for

example, as a guide in actual clinical practice), itself is a proxy for contact quality *per se* as defined hereinabove. Potentially, dielectric contact quality is a predictor of procedure results comparable to, or even better than contact force.

Reference is now made to FIG. 1C, which is a simplified and schematic plot of contact force and dielectric contact quality as a function of time and advancement of probe **111** against a cyclically moving tissue wall **50**, according to some embodiments of the present disclosure.

The features of FIG. 1C are generally the same as for FIG. 1B, with the exception that a cyclical motion **51** of tissue wall **50** has been introduced. This is a typical situation, for example, when applying a probe to a heart wall. In some embodiment of the invention, dielectric contact quality is measured as part of a tissue ablation procedure by means of an ablation probe applied to a heart wall (an atrial wall, for example). Physiological motion (for example, the beating of the heart and/or respiration) potentially produces time-varying contact quality (indicated, for example, by range **51A**). Plots of both contact force **65** and dielectric contact quality **66** are shown. Plot **66B** shows a motion-corrected contact quality force-equivalent, for reference. Optionally, a dielectric contact quality scale is reported as the instantaneous contact quality. Additionally or alternatively, in some embodiments, dielectric contact quality is corrected for motion, for example, by time averaging, filtering, or another signal processing method.

Moreover, in some embodiments, a scale of dielectric contact quality optionally takes physiological motions into account as being themselves indicative of contact quality. In the example shown, large changes occur within the range of acceptable contact, while changes are smaller as contact is initiated, and/or as contact becomes excessive. It is to be understood, however, that the actual relationship between impedance swings and contact quality may be different, according to what is observed in calibrating a scale of dielectric contact quality for a particular probe, tissue, and/or procedure.

Reference is now made to FIG. 1D, which schematically represents rotation of a catheter probe **111** through a range of contact angles **67** with a tissue wall **50** for measurement of a dielectric contact quality therebetween, according to some embodiments of the present disclosure. Reference is also made to FIG. 1E, which

schematically represents a catheter probe **111** comprising a contact force sensor **71**, according to some embodiments of the present disclosure.

In some embodiments, contact of probe **111** with a tissue contact region **106** comprises contact at an electrode **103** which is shaped (for example, rounded) to present a substantially similar contact geometry through a wide range of contact angles **67** as it moves between a first position **111C** and a second position **111D**. For a given resulting force applied by probe **111** in a direction orthogonal to tissue wall **50**, it can be understood that the resulting contact surface area (and so, to a close approximation, the contact quality of that contact) should be the same in all positions. However, the determination of the forces experienced by the probe along these directions is potentially prone to error from a single-direction contact force sensor **71**. If force sensor **71** is aligned to sense force along direction **70**, for example, then it will potentially only sense the component of contact force **72** which is aligned with direction **70**. At least a portion of the component of contact force **72** aligned with direction **69** is potentially unobserved, leading to contact angle dependence for force sensed by contact force sensor **71**. Addition of one or more additional sensors (for example, to sense lateral forces) can raise engineering difficulties, since the catheter probe **111** itself is likely to be highly constrained in diameter (leaving little room for extra wiring, or even for the extra sensor itself).

In some embodiments, dielectric contact quality estimation is substantially constant (for example, constant within about 5%, 10%, 15%, or another smaller or intermediate value) while contact angle **67** is within 30° of a central angle of contact; for example, a central angle of contact comprising orthogonal positioning of probe **111** to tissue wall **50**. Optionally, the angular range of substantially constant dielectric contact quality estimation is within 45°, 60°, 75°, or another larger, smaller, or intermediate angle from the central angle of contact.

Reference is now made to FIG. 1F, which is a simplified and schematic plot of contact force and dielectric contact quality as a function of time and angle of probe **111** against a cyclically moving tissue wall **50**, according to some embodiments of the present disclosure.

Contact force/quality traces **65**, **66**, and **68** are shown as a function of time and angle of probe with a tissue contact region **106**, the angle changing in the direction of

arrow **67** (shown as an arc in FIG. 1D). Cyclical motion of tissue wall **50** is also included in the traces. Trace **65** represents an actual contact force orthogonal to tissue wall **50**, while trace **68** represents a contact force estimated from a contact force sensor **71** aligned to sense force exerted along the longitudinal extent of probe **111**. As shown in the example, the sensed force increasing underestimates the true force as the contact angle deviates from true vertical, indicated by mark **73**.

A potential advantage of dielectric contact quality measurement, in some embodiments, is that the resulting scale (measurements shown as dielectric contact quality trace **66**) is optionally independent of contact angle. Optionally, this is a natural consequence of the measurement, particularly if the geometry of the contact surface is what dominates the impedance measurements. Additionally or alternatively, even if impedance itself has some angular dependence for a particular electrode configuration, the scale by which it is converted to a measure of dielectric contact quality may be calibrated to compensate. This option arises, for example, if there are one or more parameters of the multi-parameter impedance measurement which sufficiently correlate with contact angle.

System for Measurement of Dielectric Properties

Reference is now made to FIG. 1G, which schematically illustrates a system **100** for the measurement of tissue dielectric properties, according to some exemplary embodiments of the present disclosure.

In some embodiments, dielectric properties of tissue are assessed for determining a quality of contact (dielectric contact quality) between an electrode and tissue. Optionally, the dielectric contact quality is used, for example, in the planning and/or creation of tissue lesions. In some embodiments, tissue lesions are made for treatment, for example, of atrial fibrillation, hypertrophic obstructive cardiomyopathy, neuromodulation, and/or tumors. Dielectric property measurements are made, for example, based on the frequency- and/or time-dependent response characteristics of an electrical circuit comprising a target tissue. In some embodiments, circuit response characteristics comprise output signals (*e.g.* changes in voltage potential) in response to one or more input signals (*e.g.*, driving frequencies).

In some embodiments, system **100** comprises an electrical field measurement device **101B**, connected to a set of catheter electrodes **103**, and a set of skin-patch

electrodes **105** to measure properties (for example, voltage potential and how it changes) of time-varying electrical field **104** therebetween. In some embodiments, electrical field measurement device **101B** comprises a power meter (e.g., an RF power meter), a volt meter, and/or an ampere meter, configured to measure power, voltage, and/or current sensed by catheter electrode **103**. The measured electrical field is generated by a field generator **101A**; optionally included together in a combined electrical field generation/measurement device **101**. In some embodiments, a catheter probe **111** comprising the catheter electrodes **103** is introduced to the region of a tissue to be ablated by means of a catheter **109**. In some embodiments, the skin patch electrodes **105** are externally applied, for example, to the body of a patient. In operation of system **100**, field **104** is induced in tissue **102** (for example, tissue of a patient's body) separating the catheter electrodes **103** and the skin patch electrodes **105**. Optionally, the electrical field also extends through a target tissue region **106**. Optionally, dielectric contact quality with target region **106** is assessed as part of guiding treatment administered through probe **111**, for example, treatment by ablation (lesion formation).

As described, for example, in relation to FIG. 2, measurements of frequency-dependent impedance in the electrical circuit(s) resulting from this configuration reflect electrical properties of tissue through which the electrical field extends (in particular, dielectric properties). The dielectric properties sensed change according to the environment of electrode **103**, and in particular, according to a degree of contact with target region **106**.

Optionally, the number of catheter electrodes is 2, 3, or 4 electrodes. Optionally, a greater or lesser number of catheter electrodes is used. Optionally, the number of skin patch electrodes is 4, 5, or 6 electrodes. Optionally, a greater or lesser number of skin patch electrodes is used.

Optionally, the characteristics of the time-varying electrical field **104** are chosen to be appropriate to a measurement function which is to be performed. Typically (for measurement functions), the frequencies of the electrical field used are in the range of 10 kHz to 13 kHz. In some embodiments, the frequencies of the electrical field used for measurement are in a range, for example, of about 8 kHz-15 kHz, 5 kHz-20 kHz, 10

kHz-25 kHz, or another range having the same, larger, smaller, and/or intermediate bounds.

Optionally, the number of frequencies used is 10 or fewer frequencies. Optionally, the frequencies are distributed evenly throughout the full range of frequencies chosen. Optionally, frequencies chosen are concentrated in some particular frequency range. Applied voltages are preferably in the safe range for use in humans, for example, 100–500 millivolts, and/or a current of 1 milliamp or less (a typical body resistance is about 100 Ω). Resulting field strengths are in the range, for example of a few millivolts per centimeter; for example, 5 mV/cm, 10 mV/cm, 20 mV/cm, or another larger, smaller, or intermediate value. Based on requirements for data acquisition, sensing time is optionally about 10 msec per measurement (or a longer or shorter period, for example, about 100 msec, or 1 second), for embodiments including fast automated switching of frequencies and/or electrode pairs.

In some embodiments, a method of correlation (for example, as described in relation to calibrating the device of FIG. 1A, herein) is optionally used to relate measured electrical properties (dielectric-related properties in particular) of tissue as a function of a degree of contact therewith to procedure results (*e.g.*, lesioning effectiveness), and/or to another measure of contact quality such as contact force. It can be understood that any sufficiently dense sampling of frequencies may be initially measured with respect to a particular system and set of tissue conditions to determine which frequencies show the most useful results. The reduction to a number practical for online use can be based on which frequencies yield data having the greatest statistical correlation with results. It has been found by the inventors that ten or fewer frequencies, distributed, for example, within the range of 10 kHz to 13 kHz, are useful to allow contact assessment. It should be noted that published permittivity and conductivity values of many tissues, including heart, are roughly linear in log:log plots over ranges of a few hundred kHz within the range mentioned, which potentially allows distinctions among tissue types to be made without a requirement for dense frequency sampling.

In some embodiments, catheter probe **111** is optionally used for ablation by RF ablation energies delivered through the catheter electrodes **103** which are also used for measurements. Optionally, catheter electrodes **103** are provided as part of a standard

catheter probe, operated with a system capable of driving, sensing and/or analyzing circuits so as to acquire data suitable for dielectric property analysis.

In some embodiments, other electrodes, another catheter probe and/or another ablation method is used, for example, cryoablation, ultrasound ablation, laser ablation, electroporating ablation, or another form of ablation.

In some embodiments, the electrical field generation and/or electrical field measurement device **101A**, **101B** is under the control of controller **120**, which itself is optionally under user control through user interface **150**. Controller **120** optionally comprises a computer with CPU or other digital hardware operating according to programmed code. Controller **120** is described herein as a multi-functional module; however, it is to be understood that functions of controller **120** are optionally distributed among two or more modules of the system.

Electrical field generation by device **101**; for example, to probe dielectric properties of the tissue environment by means of impedance measurements, is under the control of controller **120**. Measurements from device **101**, for example, of impedance parameters used in measuring dielectric properties, are communicated back to the controller **120**, and/or a measurement module **120A**. In some embodiments, controller **120** also comprises an ablation controller (not shown). Ablation is optionally via electrical fields (*e.g.*, RF electrical fields) generated by device **101**, or by another ablation method, for example as described herein.

In some embodiments, controller **120** comprises contact characterization module **120B**, relating measurements to one or more additional parameters to produce a measure of dielectric contact quality. For example, state inputs provided at **140** optionally comprise any state relevant to the measurements, including, for example, details of the anatomy of tissue **102** and/or target region **106**. Optionally, position inputs **135** are provided to define position(s) of catheter electrode **103** and/or skin patch electrodes **105** relative to anatomy.

In some embodiments, details of anatomy comprise image data giving tissue types in positions through which field **104** is induced. Optionally, details of anatomy comprise a dielectric property model of the anatomy, for example, dielectric properties inferred from image data and/or typical dielectric properties of different tissue types. Optionally, the model is refined by additional data received by electrode sensing, for

example, sensing from catheter electrodes **103** and skin patch electrodes **105**. In some embodiments, user interface **150** is provided with means for governing how controller **120** uses available state inputs **140** and/or position inputs **135** — for example, to review and/or correct data-to-model registration, adjust model parameters, and the like.

Optionally, system **100** comprises correlation data structure **130**, functionally connected with controller **120**. In some embodiments, the correlation data structure comprises data by which measured electrical field properties (in particular, those associated with dielectric properties of target tissue) are linked to dielectric contact quality. The linkage is optionally (for example) by statistical correlation, by use of a machine learning result, and/or by use of equations fit to correlation data. In some embodiments, correlations are supplemented by modeling of the effects of one or more physical properties: for example, temperature, and/or time-varying filling with fluid (such as blood) and/or gas (such as air). In some embodiments, the data structure is compiled by the application of one or more of such linkage methods to previously recorded calibration data. For example, calibration lesions are formed, and separate measurement of dielectric properties and corresponding lesion sizes (and/or other lesion state information, such as lesion type and/or condition) are performed. In some embodiments, contact force is measured along with measurements for dielectric contact quality, and correlation data structure **130** is built based on correlations between these two measures. Optionally, additional data, for example, state data such as is provided by state inputs **140**, is also measured.

In some embodiments, the relationships among measurements are stored in correlation data structure **130** in such a way that a vector of dielectric properties from field generator/measurement device **101**, optionally supplemented by information from state inputs **140**, can be used to estimate dielectric contact quality (optionally, contact quality expressed as contact force). In some embodiments, correlation data structure **130** also comprises information relating to other tissue properties, for example, properties of an existing, targeted, or developing lesion. Lesion properties include, for example, lesion size (*e.g.*, lesion depth, width, and/or volume), and/or type or condition (*e.g.*, reversible, irreversible, transmural, fibrotic, and/or edematous). In some embodiments, dielectric contact quality is continuously variable, for example, expressed in arbitrary units, or in force-equivalent units. In some embodiments, dielectric contact quality

comprises a category assignment—for example, contact is estimated as being within one of a plurality of contact quality categories (*e.g.* "insufficient", "sufficient", or "excessive" with respect to one or more criteria of a procedure such as a lesioning procedure). Optionally, an impedance contact quality assessment is associated with an estimate of likelihood; for example, a standard deviation and/or a confidence level.

Measurement of Dielectric Properties

Reference is now made to FIG. 2, which is a flowchart of a method for the measurement of tissue dielectric properties for determination of contact quality, according to some exemplary embodiments of the present disclosure.

Before stepping through the blocks of FIG. 2 in detail, there is now provided a brief overview of impedance measurement. To describe a basic measurement of impedance, the following notation is used:

W — A set of frequencies.

C — A set of catheter electrodes.

P — A set of patch electrodes.

Parameters and/or values for each of the above are, for example, as described in relation to FIG. 1G.

Impedance measurements are optionally expressed as: $\mathbf{Z}(t) = \{Z_{w,c,p}(t) | w \in \mathbf{W},\ c \in \mathbf{C},\ p \in \mathbf{P}\}$ where $\mathbf{Z}(t)$ is the complex impedance (resistance and reactance) measured at time t and frequency w between a catheter electrode c and a patch electrode p.

Correlation information from any single electrode pair and/or frequency is generally not a sufficient basis on which to draw conclusions. It is a potential advantage to have numerous vector components (for example, measurements at multiple frequencies between multiple electrode pairs) in order to extract sufficiently strong correlations to allow dielectric contact quality assessment. Optionally, the number of catheter electrodes is 2, 3, or 4 electrodes, or a greater or lesser number of catheter electrodes. Optionally, the number of skin patch electrodes is 4, 5, or 6 electrodes, or a greater or lesser number of skin patch electrodes. Optionally, 2–10 electrical field frequencies are used, or a greater number of frequencies.

Herein, determination and application of correlations is described in terms of vectors, for convenience of presentation. It should be understood that in some embodiments, correlations are additionally or alternatively expressed in another form.

In some embodiments, multivariate nonlinear regression and/or classification analysis is used to establish correlations and/or mappings between measurements (and/or intervals of measurements obtained as a time series) and one or more of contact quality and contact force. Optionally, correlation and/or mapping is derived from use of a machine learning technique; for example: one or more implementations of decision tree learning, association rule learning, an artificial neural network, inductive logic programming, a support vector machine, cluster analysis, Bayesian networks, reinforcement learning, representation learning, similarity and metric learning, and/or another technique taken from the art of machine learning. Optionally, the choice of technique influences the storage, expression, and/or retrieval of correlation data. For example, correlations are optionally established and/or read-out by use of a machine learning paradigm expressed as an artificial neural network expressed in terms of connected nodes and connection weights. In some embodiments, determined correlations are expressed in terms of associative rules; for example, one or more functions (optionally fitted to the calibration data) and/or lookup tables.

In some embodiments, determined correlations are expressed in terms of associative rules; for example, one or more functions fitted to the calibration data. In some embodiments, correlations are expressed in terms of one or more dielectric measurement profiles. For example, occurrence of a certain degree of contact (*e.g.*, as measured by a force sensor) is observed during calibration to correlate with one or more impedance measurements occurring within one or more corresponding ranges. These ranges are optionally established as a dielectric property profile that serves as an indication of the corresponding degree of contact when it is observed. Alternatively or additionally to calibration with reference to another measure of contact quality, impedance contact quality measurements are correlated with the effects of carrying out a procedure (such as ablation) when a certain impedance contact quality is obtained. It should be noted that this latter procedure potentially tends to conflate non-contact parameters affecting dielectric measurement into results unless calibration also accounts

for at least one variable which is contact-related (even if not describing contact itself), such as a distance of electrode advance against a target tissue.

Use of multiple field measurements potentially assists in the isolation of correlations between field measurements and dielectric contact quality. For example, it can be considered that a substantially common tissue region near (and, in particular, contacting at least one of) each catheter electrode c_i contributes to the impedance $Z_{w,c,p}(t)$ measured between each pair of electrodes $\left(c_i,\ (p_1,...p_m)\right)$. This common region potentially increases correlation in impedance measurements made between each of those electrode pairs. Conversely, the impedance contributions of tissue more distant from the electrode probe, separating the electrode probe and any given patch electrode p_j are potentially encoded in correlations between each of the pairs $\left((c_1,...c_n),\ p_j\right)$.

Even though the impedance interactions of the different tissues (near-catheter and far-from-catheter) are potentially non-linear in their combined effects on measurements, it can be understood based on the foregoing how contributions of local and distant tissue are potentially separable from one another based on correlation properties.

Different tissues have different dielectric properties, providing one basis on which increasing contact with a tissue can have an effect on those properties. An electrode within a heart, for example, is potentially in contact with both blood and a wall myocardial tissue to varying degrees as an impudence contact quality with the myocardial tissue changes. Published values of dielectric properties in different tissue types show that blood and cardiac muscle, for example, comprise two potentially distinguishable tissue environment components. Features of tissue and tissue environments such as blood which affect dielectric properties (*e.g.* components of impedance) potentially include, for example, cellular organization, fibrous organization, and/or the presence of free fluid and/or the make-up of free fluid constituents.

Referring now to FIG. 2, prior preparation of a subject is presumed to have been performed before entry into the flowchart at block **250**. In some embodiments, skin patch electrodes are positioned on the body of a patient, in good electrical contact therewith. Optionally, the patch electrodes are, for example, about 5–15 cm across. Optionally, 3-5 skin patch electrodes are used, *e.g.*, 3 electrodes.

At block **250**, in some embodiments, catheter electrodes are brought into position, for example, by navigation through a catheter to a tissue region (for example, left atrium) at which lesions exist and/or are to be created. Optionally, at block **251**, the position is determined (*e.g.*, from co-ordinates provided by catheter navigation system), and converted to position inputs **135** for later use as will be described in relation to block **254**.

At block **252**, in some embodiments, fields of selected frequencies are applied between catheter electrodes **C** and skin patch electrodes **P** to obtain measurements of impedance. Measurements of field **104** (for example by field measurement device **101B**) allow determination of a characteristic impedance at each frequency, and for each electrode selection, which produce the set of impedance measurements $\mathbf{Z}(t)$.

At block **254**, an impedance contact quality determination is made. Determination of dielectric contact quality optionally comprises interpretation in view of a current environment (*e.g.*, rough position in a body) of catheter electrodes **C**, as provided, for example, by position inputs **135** and/or state inputs **140**. In some embodiments, time history of state inputs is taken into account; for example, oscillations as a function of heartbeat and/or respiration, and/or maximum/minimum values recently recorded. Use of inputs additional to impedance measurements provides a potential advantage by constraining conditions of the measurements so that variables relating to impedance contact quality can be isolated.

In some embodiments, recorded data (comprising impedance and associated condition data) is expressed as a time series such as: $\mathbf{X}(t) = \big(\mathbf{Z}(t),\ \mathbf{A}(t)\big),\ t = t_0, t_1, t_2, \ldots$, wherein $\mathbf{X}(t)$ represents all measurements as a function of conditions and measurements, $\mathbf{Z}(t)$ is the impedance component of the measurements, and $\mathbf{A}(t)$ represents associated conditions of the impedance measurements, for example, known anatomical attributes, other prior information, or other simultaneously determined information (for example, organ type, and measurement location).

In some embodiments, $\mathbf{X}(t)$ is related to another vector $\mathbf{Y}(t)$ describing an assessment of contact with the tissue, based on use of calibration information in correlation data structure **130**. Calibration is described, for example, in relation to FIG. 1A, herein. In some embodiments, calibration of the procedure comprises, for example, statistical analysis and/or machine learning which determines correlations

between separately determined states of $\mathbf{Y}(t)$ and $\mathbf{X}(t)$. In operation, these correlations are used to select likely existing states described by $\mathbf{Y}(t)$ based on observed states of $\mathbf{X}(t)$.

At block **256**, in some embodiments, dielectric contact quality is reported. Dielectric contact quality is optionally reported according to a scale which either reports $\mathbf{Y}(t)$ directly, or is a transform of $\mathbf{Y}(t)$. Optionally, dielectric contact quality is reported as a value in arbitrary units, and/or as a value in units which correspond to a reference scale, for example, contact force (*e.g.*, in units of equivalent force, equivalent gram-force, or another reference-equivalent unit). Optionally, dielectric contact quality is reported as a categorizing assessment of contact quality. In some embodiments, the categories comprise:

- **Insufficient** dielectric contact quality (for achieving the purpose at hand, for example, lesioning);
- **Sufficient** dielectric contact quality (for the same purpose); and/or
- **Excessive** contact quality (*e.g.* contact which is associated with a dangerous amount of contact force, so that there is a significant risk of perforation or other unintended damage to the contacted tissue wall).

An example of a simultaneous graphical presentation of dielectric contact quality information in categorized, arbitrary unit, and contact force-equivalent form is described herein in relation to FIG. 4.

At block **260**, in some embodiments, there may be a side-branch of the contact quality assessment loop during which ablation—or another procedure to which dielectric contact quality is relevant—is optionally performed. Optionally, ablation is performed in parallel with a sequence of loops passing blocks **250–258**; with additional and/or continuing ablation performed during each loop. Optionally, entry into block **260** and/or control of ablation within block **260** is at least partially dependent on a dielectric contact quality assessment. For example, initiation of ablation is optionally blocked and/or yields an alert at user interface **150** if contact quality is insufficient (additionally or alternatively, excessive) for safe and/or reliable lesioning. In some embodiments, an ongoing treatment procedure (such as an ablation) is controlled based on contact quality. For example, a power or other parameter of an ablation treatment (such as power supplied to an RF ablation probe) is optionally adjusted in coordination with variations

in contact quality. Optionally, during an ablation, an ablation parameter is adjusted based on changes to contact quality. For example, ablation power is raised to compensate for lowered contact quality and/or lowered to compensate for higher contact quality (*e.g.*, as may occur due to motions of heartbeat and/or respiration). Optionally or additionally, another ablation parameter is adjusted; for example, frequency, phase, electrode selection, signal timing, or another parameter of ablation. This provides a potential advantage for improving uniformity and/or predictability of lesioning in dynamic conditions. In some embodiments, whether or not to ablate during a particular loop is determined based, for example, on an estimate of contact quality being in and/or remaining in an acceptable range. If paused, the ablation optionally continues during a subsequent loop where appropriate conditions are restored.

For reference, it is noted that in catheterized ablation treatment of atrial fibrillation, a typical targeted time of RF ablation (for each of an optional plurality of ablation foci) is, for example, within about 10–30 seconds, 10–40 seconds, 10–60 seconds, or within another range of times having the same, higher, lower, and/or intermediate values. When heating tissue to ablate, for example by RF ablation, typical average power delivery is, for example, about 10 W, 20 W, 30 W, 35 W, or another larger, smaller, or intermediate value. Typical radio frequencies used with RF ablation are, for example, in the range of about 460–550 kHz; and commonly about 500 kHz. It is to be understood that, optionally, another ablation modality is used.

In some embodiments, treatment (ablation heating energy, for example) is delivered through the same electrode(s) as are used for measurement of impedance values reflecting dielectric contact quality with tissue, *e.g.*, as RF energy at a frequency inducing appropriate "resistive" losses in the tissue which result in tissue heating. It is a potential benefit to ablate and measure using the same electrodes. For example, it can result in less instrumentation required, less positioning coordination required, and/or a more direct relationship between measurements made and results achieved. Additionally or alternatively, in some embodiments, measurements and ablation are performed by separate instruments (however, in this case, at least some form of mechanical coupling and/or contact between the instrument probes should be provided for so that the dielectric contact quality measurement is relevant to the effects of the treatment probe). As also mentioned hereinabove, ablation is optionally by any ablation method known.

At block **258**, in some embodiments, a determination is made as to the continuation of the procedure. If the procedure continues, flow returns to block **250**. Otherwise, the procedure ends.

Display of Dielectric Contact Quality

Reference is now made to FIG. 4, which illustrates a graphical user interface (GUI) widget **400** for display of dielectric contact quality information to a user, according to some exemplary embodiments of the present disclosure. Optionally, features of GUI widget **400** described hereinbelow are additionally or alternatively provided by separate displays. However, there is a potential advantage to providing a single display to allow at-a-glance status determination.

In some embodiments, a display function of user interface **150** comprises a display such as GUI widget **400**. In some embodiments, GUI widget **400** comprises one or more indications of contact quality between a probe **111**, **112** and a target tissue region **106**. In some embodiments, one such indication comprises a dielectric contact quality scale **402**. Optionally, scale **402** distinguishes a plurality of regions (*e.g.*, regions **402A**, **402B**, **402C**), which indicate different qualitative contact quality states. For example, scale region **402A** optionally represents insufficient contact (*e.g.*, contact ineffective for the production of a therapeutic result). Scale region **402B** optionally represents excessive contact (*e.g.*, contact which represents a potential danger of trauma such as organ perforation). Scale region **402C** optionally represents a range within which contact is sufficient. In some embodiments, a scale marker **405** is provided which gives a relative quantitative assessment of contact quality. The scale is optionally in arbitrary units. Optionally, movement of scale marker **405** along the scale is continuous, or divided into unit steps.

In some embodiments of the invention, a force indication **404** is provided as part of GUI widget **400**. In some embodiments, force indication **404** is provided in force-equivalent units (*e.g.*, grams-force). A potential advantage of this display is to allow operators to perform procedures based on guidelines originally defined in terms of contact force (*e.g.*, as measured by a probe force sensor), without a requirement to translate into another unit.

In some embodiments, one or more additional features are provided relating to dielectric assessment of tissue at a contact region. In some embodiments, dielectric

measurement is also used to determine one or more parameters of the tissue itself. For example, GUI widget **400** includes a tissue thickness indication **408** (*e.g.*, giving an estimated tissue thickness in mm); and/or a lesion depth indicator **406**. Lesion depth indicator **406** optionally comprises a graphical illustration of measured and/or predicted lesion geometry. For example, the peak of the hill arising from the center of indicator **406** optionally represents the maximum depth of a tissue ablation lesion which is currently being assessed, and/or which is planned for ablation. The circumference of the hill optionally represents an estimated lesion diameter.

It should be understood that the graphical representation of these functions optionally assumes other forms; the specific graphical representations of GUI widget **400** comprise an illustrative example of how various indication functions are optionally combined.

Examples of Dielectric Contact Quality as a Predictor of Contact Force

Reference is now made to FIG. 5, which is a graph presenting estimates of contact force derived from dielectric contact quality measurements, the estimated contact forces being plotted with respect to directly sensed contact forces, according to some embodiments of the present disclosure.

To generate data for this graph, contact force was measured by a force sensing probe pressed against an *ex vivo* preparation of myocardial tissue (porcine right ventricle tissue at physiological temperature). Corresponding dielectric contact quality was determined by dielectric property measurements, made for example as described in relation to FIG. 2 herein, and converted by means of a classifier to a contact force equivalent. The classifier was constructed based on a separate set of calibration measurements, for example as described in relation to FIG. 1A, herein. For all measurements, the root mean squared error (RMSE) between actually measured and estimated contact force was about 8.4 grams-force.

It can be seen from the graph that the classification results produced a strong linear trend, deviating to an under-estimation (and somewhat larger error) near the top of the tested force range. This deviation potentially corresponds to less distinguishable force levels in the upper range; for example, as other parameters of contact to which dielectric contact quality is sensitive (*e.g.* area of contact) approach maximum values.

Reference is now made to FIG. 6, which is a graph of receiver operating characteristic (ROC) presenting for the data of FIG. *5* a true positive rate versus false positive rate for dielectric contact quality-based estimation of contact force above a threshold of 75 grams-force, according to some embodiments of the present disclosure. It should be understood that each point along the ROC graph corresponds to different multiparameter dielectric readings which have been mapped to the estimated contact force on which the ROC graph is based.

On an ROC graph, true positive rate corresponds to sensitivity (Y axis; higher is more sensitive), and false positive rate corresponds to 1-specificity (X axis; further left is more specific). Perfect classification (100% sensitivity and specificity) would appear as a point in the upper left corner of the graph; the diagonal line is the line of no classification (chance). For the 75 grams-force threshold, the graph shows an area under the ROC curve of about 95% of the total graph area. This fairly high value appears to corroborate conclusions described above with respect to FIG. 5.

Reference is now made to *Figure 10*, which is a graph presenting dielectric property-estimated contact force vs. directly measured force, according to some exemplary embodiments of the invention.

On the vertical axis, values represent the returned contact force estimate (in grams-force) of a contact force estimator operating on dielectric measurements. On the horizontal axis, values represent grams-force measured by a TactiCath™ catheter probe from St Jude Medical (legacy Endosense system). Measurements were made with respect to contact with porcine left atrium wall. Open (white centered) plot points represent corresponding data points (measurements made through the same catheter, either dielectrically or via the force sensor). Darkened (gray-centered) plot points represent the unity line of the direct force measurements plotted against themselves.

Reference is now made to *Figures 11A* and *11C*, which graph contact force measurements using a TactiCath™ catheter (as described in relation to *Figure 10*). Reference is also made to *Figures 11B* and *11D*, which graph contact quality level estimates made based on dielectric measurements (also as described in relation to *Figure 10*). The epochs in minutes of *Figures 11A–11B* correspond to one another; as is also the case for *Figures 11C–11D*. In *Figures 11B* and *11D*, the contact levels are set between 0 and 1.0 for estimated contact forces below 10 grams-force; between 1.0 and

2.0 for estimated contact forces between 10 and 25 grams-force; between 2.0 and 3.0 for estimated contact forces between 25 grams-force and 40 grams-force, and between 3.0 and 4.0 for estimated contact forces above 40 grams-force.

Reference is now made to TABLE 1, which displays in tabular form data from the experiments outlined in *Figures 10-11D*. The data from both measurement types (directly measured contact force and estimated contact quality) have been converted to force levels of low, optimal, high and exceed, which use the same respective thresholds (< 10 grams-force, 10-25 grams-force, 25-40 grams-force, and > 40 grams-force) as are also shown in *Figures 11B* and *11D*. It should be noted that the estimated contact quality categorization may be considered "safe" with respect to values in the "exceed" category (the category of potentially unsafe levels of contact force), since the estimator makes the "exceed" categorization at the same level of contact, or a lower level of contact, than the categorization based on the measured contact force.

Table 1

		Measured Contact Force Category			
		Low	*Optimal*	*High*	*Exceed*
Estimated Contact Quality Category	*Low*	**87%**	3%		
	Optimal	13%	**85%**	10%	
	High		12%	**85%**	12%
	Exceed			5%	**88%**

3-D GUI Widget for Organ View Orientation

Reference is now made to FIG. 7A, which schematically illustrates a view of a graphical user interface (GUI) widget **700**, representative of the 3-D orientation of the atria of a heart in space, according to some embodiments of the present disclosure. Reference is also made to FIG. 7B, which schematically illustrates a heart **750** in an orientation corresponding to the orientation of GUI widget **700**, according to some exemplary embodiments of the present disclosure.

In some embodiments, a GUI widget **700** comprises a schematic graphical representation of an anatomical structure; for example, at least a portion of a heart **750**. The schematic graphical representation is optionally implemented, for example, as a 3-D model and/or as a set of 2-D icons representing views of the anatomical structure in

different orientations. In some embodiments, the widget **700** comprises a dynamic icon, changing appearance according to a virtual orientation of the schematic graphical representation. In some embodiments, the schematic graphical representation includes one or more reference bodies (for example, atrial representations **702**, **704**); distinguishable in their orientation by their spatial relationships to each other, and/or by one or more indicating features (*e.g.* vascular segments **712** and **714**, and/or valve indicators **722** and **724**). Optionally, the indicating features protrude from the reference bodies **702**, **704**. In this and following examples, shading is also used as a distinction, with the right atrium **752** or its right atrial representation **702** (and associated features) being shaded in light gray, and the left atrium **754** or its left atrial representation **704** (and associated features) being shaded in dark gray. Optionally, color, texture, or another aspect of visual appearance is used to help emphasize distinctions. For example, the left atrium is optionally colored red and/or orange, and the right atrium blue and/or green.

Optionally, atrial representation **702** corresponds to right atrium **752** of a heart **750**, atrial chamber representation **704** corresponds to left atrium **754** of a heart **750**, vascular segments **712** correspond to right atrium connected segments of the superior and/or inferior vena cava **762**, vascular segments **714** correspond to left atrium connected segments of the pulmonary veins **764**, valve indicator **722** corresponds to the tricuspid valve leading from the right atrium **752** to right ventricle **772**, and/or valve indicator **724** corresponds to a mitral valve leading from left atrium **754** into left ventricle **774**.

In some embodiments, GUI widget **700** is provided as a reference for assisting determination of the orientation of a corresponding view of a heart **750**. For example, GUI widget **700** is displayed on a screen alongside a view of heart **750**, in a 3-D orientation suitably corresponding to the displayed 3-D orientation of heart **750**.

Optionally, widget **700** is linked to GUI inputs so that it also acts as an orientation control. For example, event handling software connected with GUI widget **700** is configured to receive click, drag, touch, swipe, and/or any other suitable user input gesture directed to (*e.g.*, on, alongside, and/or passing over) the displayed GUI widget **700**. Optionally, the event handling software in turn induces rotation of the displayed view of GUI widget **700** and an associated view of heart **750** in synchrony,

based on the user input gestures. Optionally, events are interpreted as simulating physical interaction; for example, simulating rotation as if motion gestures are contacting the displayed surface of the GUI widget and causing it to rotate in the gesture direction. Optionally, the event handling software defines hotspots for selection of particular views. For example, clicking on (or otherwise indicating) a particular region of GUI widget **700** optionally triggers re-orientation of that region to face the operator. Additionally or alternatively, indicating a particular region alongside GUI widget **700** triggers a rotational step (for example a change in orientation of 90°). In some embodiments, rotation of GUI widget **700** is triggered by input events to other controls/display elements; for example, gestures which simulate direct manipulation of a view of the heart **750**, inputs to sliders, automatic view changes in response to navigation movements of a catheter probe, *etc.* It should be understood that the input and handling examples provided are non-exhaustive, and not limiting of the scope of the concept.

In some embodiments, GUI widget **700** is used to assist in manipulating and/or comprehending an anatomically correct view of a heart **750**, optionally in conjunction with the positioning and orientation of treatment tools, such as catheter probes. Even though the physician is well familiar with the anatomy of an organ targeted for treatment, computer-visualized surgery can present a very wide range of views which may themselves create opportunities for confusion. For example, anatomical views are optionally presented as solid, transparent, partially transparent, and/or cutaway images; each of which obscures or reveals anatomical landmarks in different ways. Additionally or alternatively, views can be presented at different scales: for example, whole-organ displays, and/or magnified views of an organ in the vicinity of a region targeted for treatment. Magnified views in particular are prone to creating confusion over position and/or orientation, since key landmarks providing visual context may be out of the frame of view. Optionally, color data is superimposed on anatomical shape data, for example, to indicate tissue health, thickness, and/or another feature. Some organs, and in particular the heart, are in constant motion, which movement in a view display optionally reflects. Moreover, structures surrounding and/or connecting to an organ (particularly in the case of the multiply connected heart) are optionally represented visually to variable extents of completeness from case to case, and/or application to

application, which can also influence the appearance of a target organ in context. It is finally mentioned that an unfamiliar orientation or an unusual distortion of an organ view can itself give rise to uncertainty. For example, the orientation of the heart in FIG. 7B (corresponding also to view **791** of FIG. 7D) is not as usually shown in anatomical textbooks, but rather shown as seen from beneath, with ventral side up, and dorsal side down. View **796** of FIG. 7D is also unusual, being an upside-down dorsal view of a heart **750**.

Optionally, features selected to help mark orientation of GUI widget **700** correspond to (without necessarily anatomically duplicating in detail) anatomical features which a physician is likely to be concerned with during treatment. Potentially, this helps to reduce the "cognitive distance" between what the physician is really looking for, and what the GUI widget **700** directly represents. For example, catheter-guided treatment of atrial fibrillation by cardiac tissue ablation optionally comprises aspects such as: reaching the right atrium **752** via a branch of the vena cava **762**, crossing the septal wall between atria for access to treatment locations within the left atrium **754**, and ablation from within the left atrium **754** of one or more regions defined by the positions of the pulmonary veins **764**. Each of these anatomical features is optionally represented by corresponding features of GUI widget **700**, for example as identified hereinabove. In contrast, it is a potential advantage to suppress features which are not directly relevant to tasks of the treatment itself, even if these are anatomically and/or functionally important otherwise. For example, GUI widget **700** optionally indicates the positions of the tricuspid valve and mitral valve (by valve indicators **722** and **724**, respectively), but optionally omits showing the ventricles to which they connect. It is also a potential advantage to avoid an excess of detail even in features that are represented: for example, the degree of schematic representation in FIG. 7A is such that the valves are represented only by bulges. Indeed, an alternative interpretation of valve indicators **722**, **724** is as shrunken representations of the ventricles themselves.

Optionally, features of the 3-D model underlying GUI widget **700**, and/or of its presentation, are provided to create a relatively consistent, rotationally distinct, appearance. Suppression of the ventricles **772**, **774**, for example, provides a potential advantage by reducing the tendency of the ventricles to obscure the atrial representations **702**, **704** and their vascular landmarks **712**, **714**. Landmarks are

preferably provided in sufficient density for identification at any orientation, without over-providing to the point that the landmarks become themselves distracting. Optional coding of structures by color and/or shading potentially helps to make it clear at a glance at least the general orientation of the GUI widget **700**.

Optionally, GUI widget **700** is constructed using shapes and/or shape relationships suggestively corresponding with shapes of actual anatomy, even though they do not literally depict them. The shapes optionally comprise an assemblage of basic geometrical figures. Vascular structures, for example, are optionally represented as straight tubes or cylinders; chambered structures as ellipsoids; aperture structures (such as valves) as flattened ellipsoids, *etc.* Optionally representation as a mesh structure is used. Use of mesh model may allow closer approximation of actual heart anatomy to be achieved. However, a potential advantage of representing identified features as simple geometrical objects is that they remain easily identifiable and/or clearly distinctive from a wide range of viewpoints. Furthermore, such shapes potentially help to free the widget from irrelevant (non-differentiating) visual information.

In some embodiments, a rough size difference among features helps to create an orienting asymmetry and/or readier identifiability. Optionally, such differences are selected to evoke similar differences in the actual anatomy. For example, right atrial representation **702** is shown slightly smaller than the more oblong left atrial representation **704**, while the vena cava branches **712** are shown larger than the pulmonary vein branches **714**. Such correspondences with anatomical relationships are not necessarily quantitative depictions of dimension ratios. However, they potentially serve a mnemonic function, by schematically evoking salient details of the actual anatomy while requiring a minimum of cognitive load to be identified.

Reference is now made to FIG. 7C, which shows views **741**, **742**, **743**, **744**, **745**, **746** of six different orientations of GUI widget **700**, separated by about 90° from each other, according to some exemplary embodiments of the present disclosure. Reference is also made to FIG. 7D, which shows the views of FIG. 7C reduced in size, alongside corresponding anatomical views **791**, **792**, **793**, **794**, **795**, **796** of a heart **750**, according to some exemplary embodiments of the present disclosure.

Arrows **730** may be understood as indicating rotation of GUI widget **700** and/or heart **750** by about 90° between the view at the base of each arrow, and the view at the

tip. The rotation may be understood as a 90° roll, comprising rotation of the surface portion nearest the viewer's position to a perpendicular orientation on the side of the rotated GUI widget **700** which is away from the arrow tip.

Heart view **791** and GUI widget view **741** correspond to the view of FIGs. 7A–7B. Both the light-shaded right atrium **752** and dark-shaded left atrium **754** are clearly visible in the anatomical view **791**.

Heart view **793** shows a conventional, top side up ventral view of a heart **750**, with the right atrium **752** clearly visible, but the left atrium largely hidden. The corresponding view **743** of the GUI widget **700**, however, shows both atria clearly. Moreover, it is easy to tell by glancing at views **741** and **743** how the two views relate to one another, since most of features remain plainly visible in each. In heart views **791**, **793**, the changing orientation leads to radical changes in apparent shape, and/or changes in which anatomical features are visible. Similar observations apply to comparisons involving views of the other orientations. It can be understood that the difference in ease of comprehension potentially becomes still more pronounced when differential shading of the heart views (shown herein primarily for purposes of explanation) is removed and/or replaced with shading serving some different purpose.

Another potential advantage of the GUI widget **700** is seen most particularly in connection by consideration of the sequence of views **742**, **743**, and **744**. Shading of the GUI widget as viewed from the side of left atrium (view **742**) is almost completely dark (using the shading conventions illustrated), while shading as viewed from the opposite side (view **744**) is almost completely light. About equal balance between the two shadings is seen in ventral view **743**. These gross differences can be discerned even in peripheral vision, which is a potential advantage for an operator whose visual attention is focused on a nearby anatomical display.

The anatomical views **791**, **792**, **793**, **794**, **795**, **796** of heart **750** are shown all at the same scale. However, it should be understood that the same orientation information is shown, in some embodiments, as the anatomical view is magnified. Optionally, some indication of such scale changes are optionally also provided on GUI widget **700**. For example, a region of viewing indicator (a rectangle, for example) is optionally superimposed on the GUI widget **700** to indicate which part of the represented anatomy is being closely inspected. Optionally, a view from within an organ (for example, from

within an atrium) is indicated by modification of the GUI widget **700**, for example, by suppressing display of the GUI widget portions representing anatomy which is "behind" the viewing port of the anatomy.

Indicators for Monitoring of Lesion Status

Reference is now made to *Figures 8A–8E*, which illustrate a display for indicating lesioning status, including contact force, to a user, according to some exemplary embodiments.

Figures 8A–8E comprise an artificially rendered image of an ablation probe **802** and its position relative to tissue **805** near to which ablation probe **802** is positioned for ablation. Optionally, the rendering is in color similar to the vital color of the tissue (black and white is shown for purposes of illustration). In some embodiments, the rendering includes a visual indication of contact pressure between the tissue **805** and the electrode **802** comprising an indented region **804**. For example, indented region **804** is shown more strongly deflected in *Figure 8B* than in *Figure 8A* (and not deflected at all in *Figure 8D*), providing an indication of relative contact force. Optionally, the depth to which indented region **804** is actually shown indented is variable depending, for example, on a measured contact force and/or contact quality value.

In some embodiments, an estimate of a quality of the lesion which would be and/or is being formed at a current site of contact is provided by a visual indication, such as circle **813**. In *Figures 8D–8E*, additional indication **810**, **812**, and **814** are also shown, indicating full or partial degrees of transmural lesioning as estimated based on pre- or post-lesion measurements. More details of such indications used for one or both of pre- and post-lesioning tissue assessment for transmurality of a lesion are discussed, for example, in relation to *Figure 9*.

In some embodiments, one or more additional indications are provided as part of the rendered image which provide an indication of how lesioning is proceeding. For example, in *Figure 8B*, "steam" is shown arising from the lesion point. Optionally, this is an indication that temperature has reached (and/or is maintained at) a certain threshold. The threshold may be, for example, a threshold at which lesioning occurs, a threshold above which a danger of effects such as steam pop or charring occurs, or another threshold. In *Figure 8C*, tissue **805** is shown relatively bleached in color, which optionally serves as an indication of the current estimated extent of lesioning.

Reference is now made to *Figure 9*, which illustrates display elements **810**, **812**, **813**, **814** which are optionally used to indicate estimated transmurality of a lesion to a user, based on pre- and post- lesioning dielectric property measurements.

In some embodiments, estimated transmurality is communicated to a user by the use of a simplified graphical element. The elements of *Figure 14* take the form of complete circles **813**, **814**, to indicate a positive estimate of lesion transmurality, and the form of incomplete circles **812**, **810** (*e.g.*, ¾ circles) to indicate a negative estimate of lesion transmurality. Optionally, inner circles **812**, **813** are used to indicate estimates based on pre-lesioning measurements. Optionally, outer circles **810**, **814** are used to indicate estimates based on post-lesioning measurements.

It is expected that during the life of a patent maturing from this application many relevant transcatheter treatments will be developed; the scope of the term "transcatheter delivery of a disease treatment" is intended to include all such new technologies *a priori*.

As used herein with reference to quantity or value, the term "about" means "within ±10% of".

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean: "including but not limited to".

The term "consisting of" means: "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

The words "example" and "exemplary" are used herein to mean "serving as an example, instance or illustration". Any embodiment described as an "example" or "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments". Any particular embodiment of the invention may include a plurality of "optional" features except insofar as such features conflict.

As used herein the term "method" refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term "treating" includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

Throughout this application, embodiments of this invention may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as "from 1 to 6" should be considered to have specifically disclosed subranges such as "from 1 to 3", "from 1 to 4", "from 1 to 5", "from 2 to 4", "from 2 to 6", "from 3 to 6", *etc.*; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example "10-15", "10 to 15", or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases "range/ranging/ranges between" a first indicate number and a second indicate number and "range/ranging/ranges from" a first indicate number "to", "up to", "until" or "through" (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

WHAT IS CLAIMED IS:

1. A method of characterizing contact quality of an intra-body probe with a target tissue, comprising:

measuring dielectric properties of the environment of an electrode of an intra-body type electrode using an electrical circuit, the electrical circuit being defined by the electrode placed intra-bodily so that the target tissue is included in the electrical circuit; and

characterizing contact between the probe and the target tissue, wherein the characterization of the contact comprises mapping of the measured dielectric properties to a mapped value within a range of values characterizing the contact quality.

2. The method of claim 1, wherein the mapped value comprises an index characterizing contact quality.

3. The method of claim 1, wherein the mapped value represents a contact force equivalent, such that a force of contact of the intra-body probe with the target tissue is represented by the mapped value.

4. The method of claim 1, wherein the range of values characterizing the contact quality comprises at least four possible values.

5. The method of any one of claims 1-3, wherein the intra-body probe comprises an ablation electrode configured for ablation of the target tissue.

6. The method of claim 5, wherein the ablation electrode comprises the electrode defining the electrical circuit.

7. The method of any one of claims 5-6, wherein the characterizing comprises evaluating sufficiency of the contact for effective lesioning by the ablation electrode.

8. The method of claim 7, comprising providing a user feedback indicating the sufficiency of contact for effective lesioning.

9. The method of any one of claims 5-8, wherein the ablation electrode is configured for the formation of a lesion in the target tissue by at least one of the group consisting of: thermal ablation, cryoablation, RF ablation, electroporating ablation, and/or ultrasound ablation.

10. The method of claim 1, comprising operating an ablation electrode based on the characterization of the contact.

11. The method of claim 10, wherein the operating of the ablation electrode is gated to occur only when the characterized contact is within a predetermined range.

12. The method of any one of claims 10-11, wherein the characterizing contact is performed iteratively during operating of the ablation electrode.

13. The method of any one of claims 10-12, wherein the operating of the ablation electrode is based on an estimated contact force of the characterized contact, such that at least one of an ablation power, a duration of ablation, a selection of an electrode, and a frequency of ablation energy, is selected based on the estimated contact force.

14. The method of any one of claims 1-10, wherein the characterizing comprises estimation of an equivalent force of contact of the probe with a surface of the target tissue.

15. The method of claim 14, wherein the estimation of an equivalent force of contact is substantially independent of an angle of contact between the probe and the surface of the target tissue.

16. The method of any one of claims 1-15, wherein the characterizing comprises evaluating a risk of perforation of the target tissue by the probe.

17. The method of claim 16, comprising providing a user feedback indicating the risk of perforation.

18. The method of any one of claims 1-17, comprising moving the probe under automated control based on the characterization of the contact.

19. The method of any one of claims 1-18, wherein the target tissue comprises cardiac tissue.

20. The method of any one of claims 1-18, wherein the target tissue comprises cardiac tissue of the right atrium.

21. The method of any one of claims 1-20, wherein the intra-body probe makes a plurality of simultaneous contacts with the target tissue, and the characterizing comprises separately characterizing each of the plurality of simultaneous contacts.

22. The method of claim 21, wherein the intra-body probe comprises an ablation electrode, and wherein the method comprises operating the ablation electrode to ablate at each of the plurality of simultaneous contacts under separate control, based on the corresponding characterizing of contact.

23. The method of claim 22, wherein the separate control comprises delivery of a separately selected at least one of a frequency, phase, or level of ablation power to each of the plurality of simultaneous contacts.

24. The method of claim 22, wherein the separate control comprises separately selected timing of delivery of ablation power to each of the plurality of simultaneous contacts.

25. The method of any one of claims 1-24, wherein the characterizing of contact is based on a data structure mapping measured dielectric properties to a characterization of contact with the target tissue.

26. The method of claim 25, wherein the character of contact comprises at least one from among the group consisting of: a risk of perforating the tissue with the intra-body probe, an estimate of contact force applied to the tissue by the intra-body probe, and/or an assessment of adequate contact for reliable ablation using the intra-body probe.

27. The method of claim 25, wherein the data structure comprises machine-learned associations applicable to the measured dielectric properties to convert them to the characterization of contact with the target tissue.

28. The method of any one of claims 1-27, wherein the dielectric properties comprise dielectric properties measured for a plurality of electrical field frequencies.

29. The method of claim 28, wherein the electrical field frequencies are in a range between about 5 kHz and about 20 kHz.

30. A device for ablation of a target tissue based on dielectric contact quality of an intra-body ablation probe with the target tissue, comprising:

the intra-body ablation probe, including at least one electrode;

an electrical field measurement device, configured to measure dielectric properties in the environment of the at least one electrode based on signals sensed by the at least one electrode; and

a contact characterization module, configured to characterize contact between the intra-body ablation probe and the target tissue, based on the dielectric properties measured by the electrical field measurement device.

31. The device of claim 30, wherein the contact characterization module comprises a data structure mapping the dielectric properties to characterization of contact.

32. The device of claim 30, comprising a display configured to display the characterized contact as an estimate of contact force.

33. The device of claim 30, wherein the electrical field measurement device comprises the at least one electrode.

34. A method of indicating the orientation of a displayed view of an anatomical structure, comprising:

displaying on a display an anatomical view of the anatomical structure in a user-adjustable orientation; and

coordinating an orientation of a displayed schematic representation of a portion of the anatomical structure to the user-adjustable orientation of the anatomical view, such that the schematic representation is displayed in the same orientation as the anatomical view of the anatomical structure;

wherein the schematic representation comprises a body portion representing a first part of the anatomical structure, and a plurality of protruding portions representing protruding portions of the anatomical structure and protruding from the body portion, such that the orientation of the plurality of protruding portions is identifiable from any orientation of the displayed schematic representation.

35. The method of claim 34, wherein the anatomical structure comprises an atrium of a heart.

36. The method of claim 34, wherein the body portion of the schematic representation comprises at least two sub-portions; each sub-portion being distinctively shaded, and corresponding to a predetermined portion of the anatomical structure.

37. The method of claim 36, wherein the anatomical view of the anatomical structure includes a view of at least one obscuring anatomical portion positioned to obscure the predetermined portions of the anatomical structure, and wherein the schematic representation omits to represent this obscuring anatomical portion, thereby preventing obscuring of the at least two portions of the schematic representation.

38. The method of claim 36, wherein each of the at least two sub-portions of the schematic representation corresponds to an atrium of a heart, and the plurality of protruding portions comprise a plurality of generally cylindrical protrusions corresponding to the number of veins feeding into each atrium.

39. The method of claim 38, wherein the plurality of protruding portions comprise a protrusion indicating a position of a heart valve.

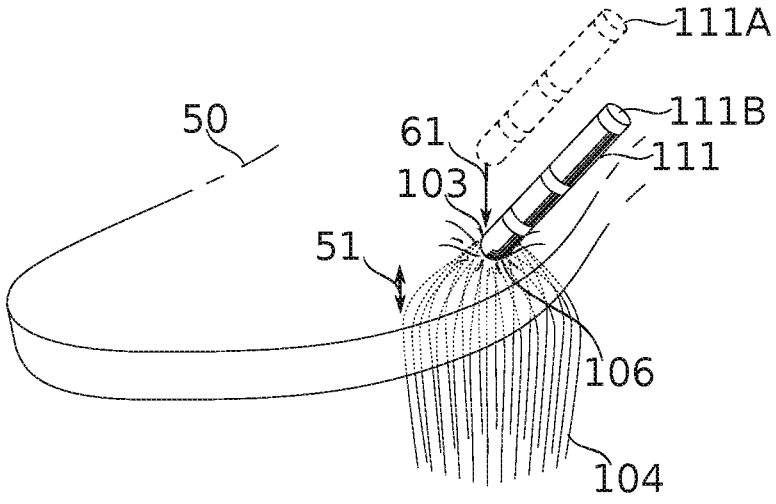
40. A method of characterizing contact quality of an intra-body probe with a target tissue, comprising:

measuring dielectric properties of the environment of an electrode of an intra-body type electrode using an electrical circuit, the electrical circuit being defined by the electrode placed intra-bodily so that the target tissue is included in the electrical circuit; and

characterizing contact between the probe and the target tissue, wherein the characterization of the contact comprises conversion of the measured dielectric properties to an equivalent contact force estimation, and wherein the estimation of an equivalent force of contact is substantially independent to an angle of contact between the probe and the surface of the target tissue.

41. The method of claim 40, wherein the substantial independence comprises a change of less than 10% through a range of angles of contact, and the range of angles of contact is within 45° of a central angle of contact.

FIG. 1A



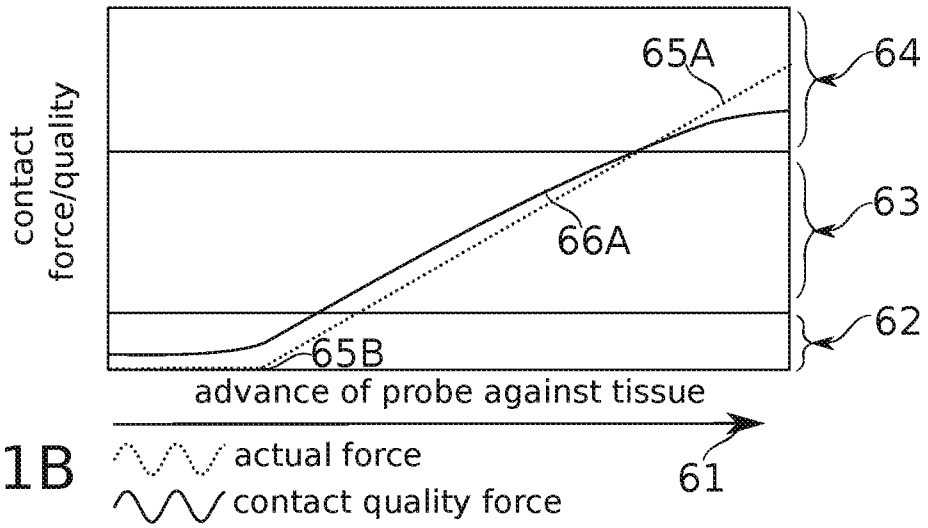


FIG. 1B

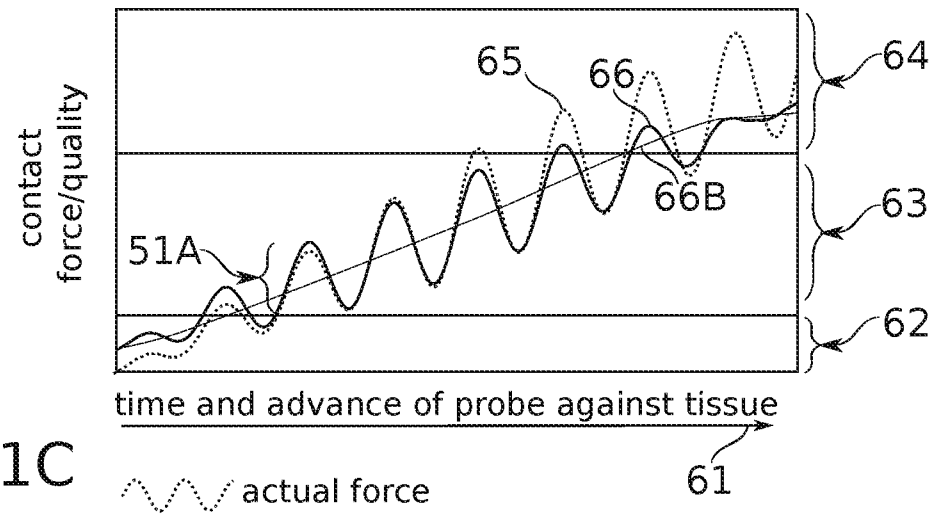


FIG. 1C

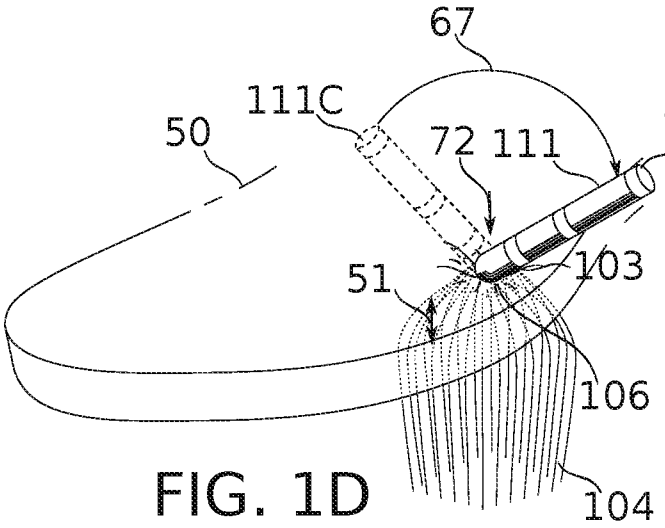


FIG. 1D

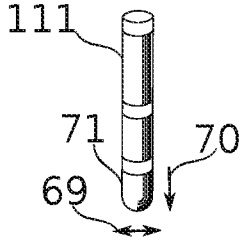


FIG. 1E

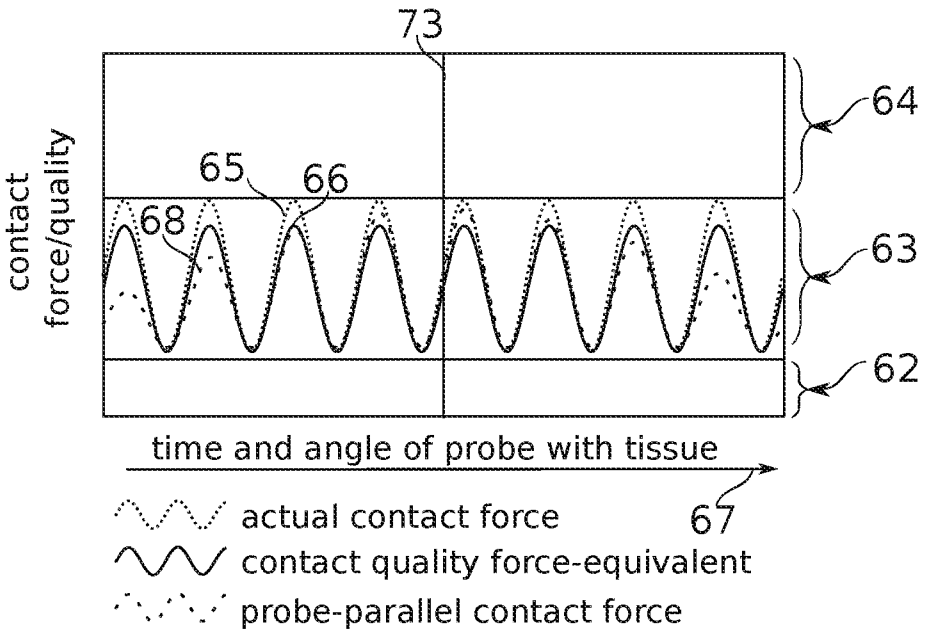


FIG. 1F

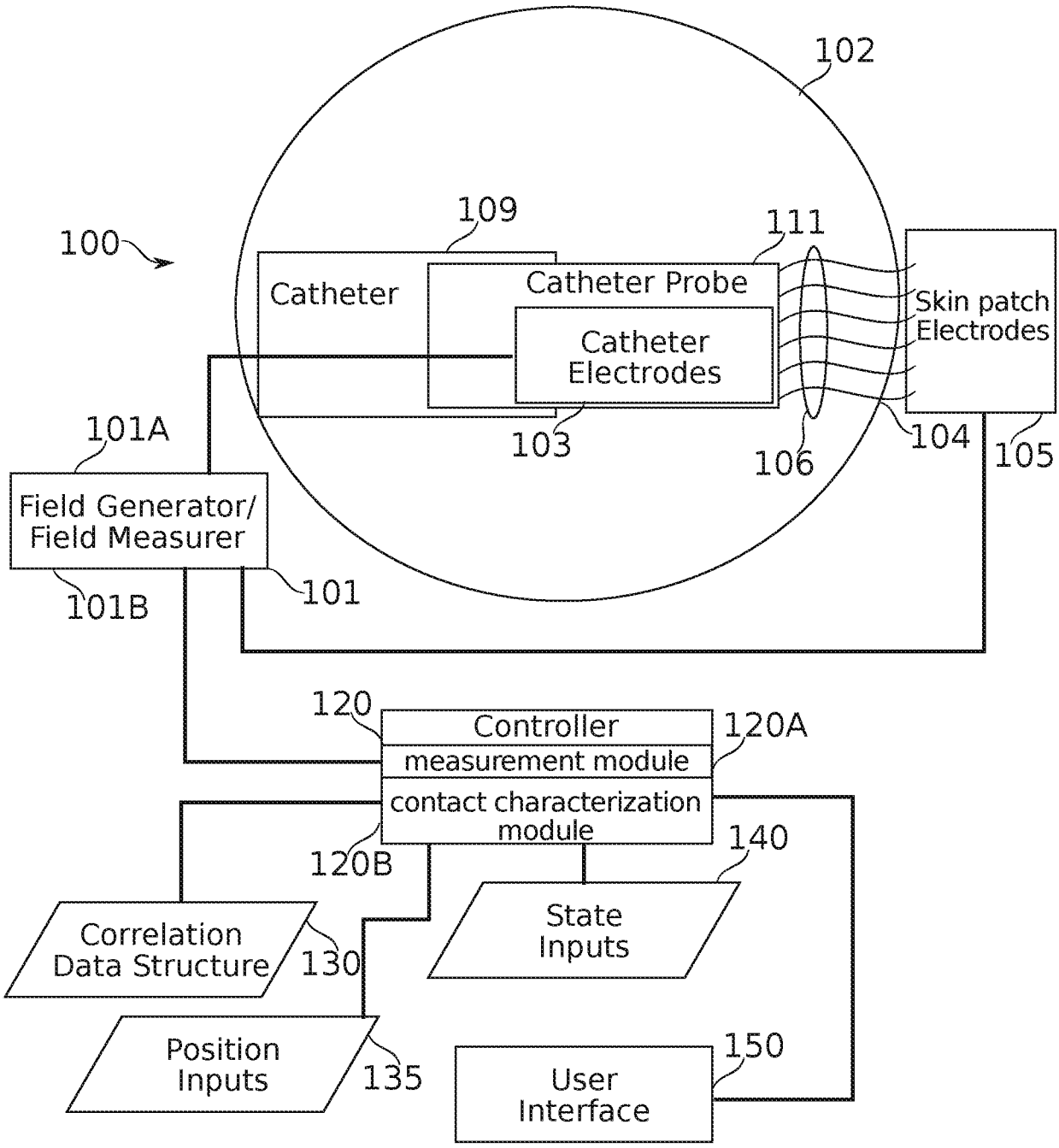

102
100
109
111
Catheter
Catheter Probe
Catheter Electrodes
Skin patch Electrodes
103
106
104
105
101A
Field Generator/ Field Measurer
101B
101
120
Controller
120A
measurement module
contact characterization module
120B
140
State Inputs
Correlation Data Structure
130
Position Inputs
135
150
User Interface

FIG. 1G

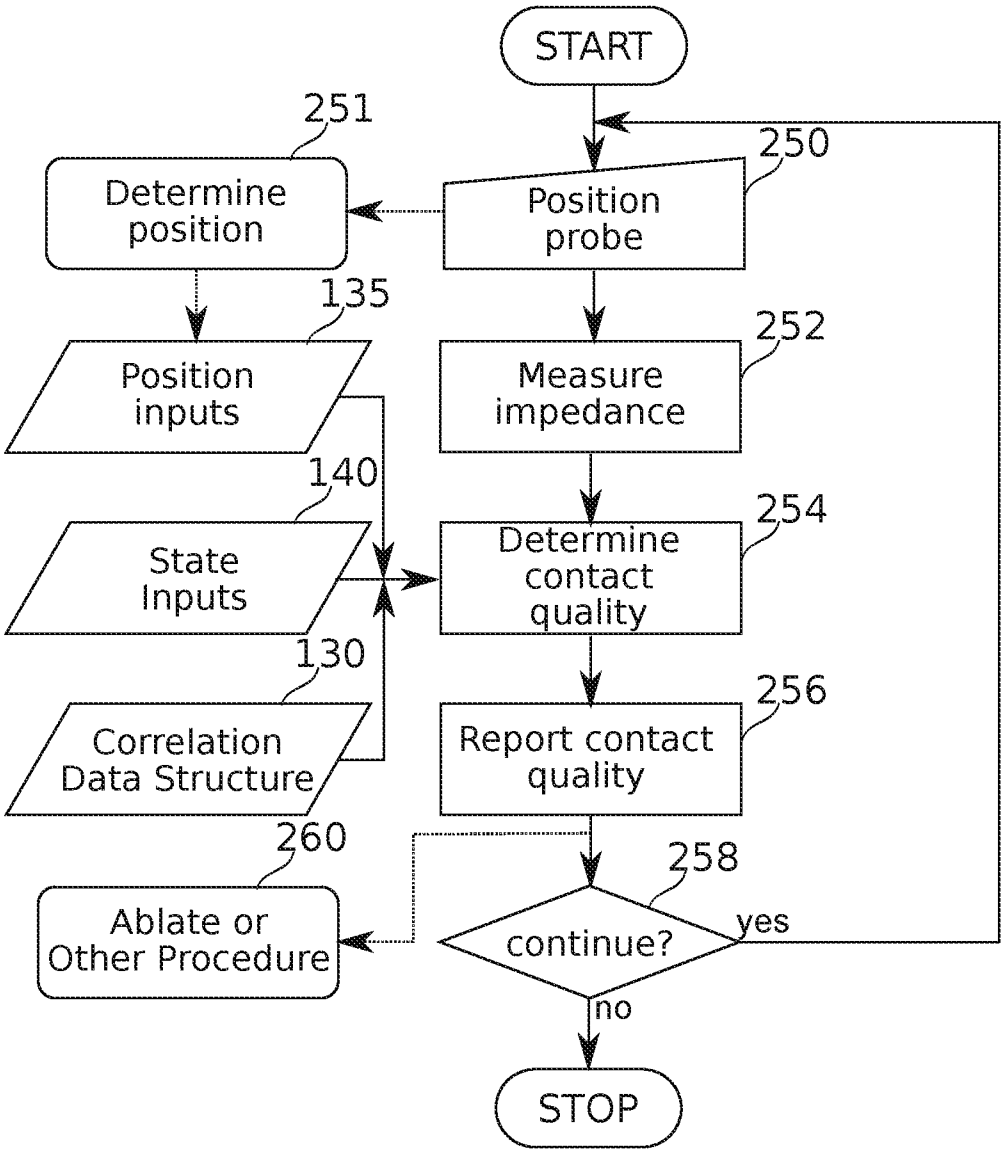

START
251
Determine position
250
Position probe
135
Position inputs
252
Measure impedance
140
State Inputs
254
Determine contact quality
130
Correlation Data Structure
256
Report contact quality
260
Ablate or Other Procedure
258
continue?
yes
no
STOP

FIG. 2

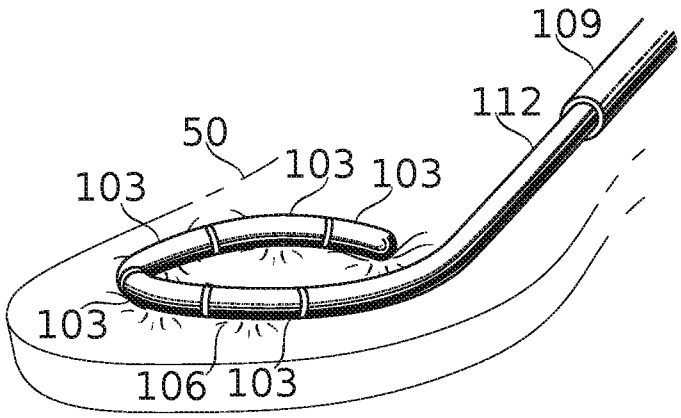

109
112
50
103
103
103
103
106
103

FIG. 3

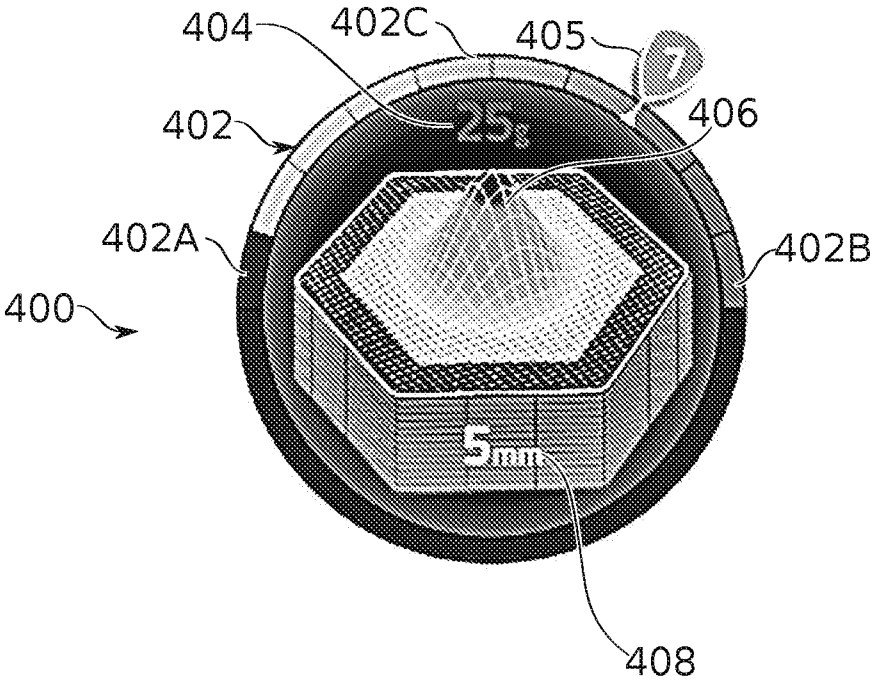

404
402C
405
406
402
402A
402B
400
5mm
408

FIG. 4

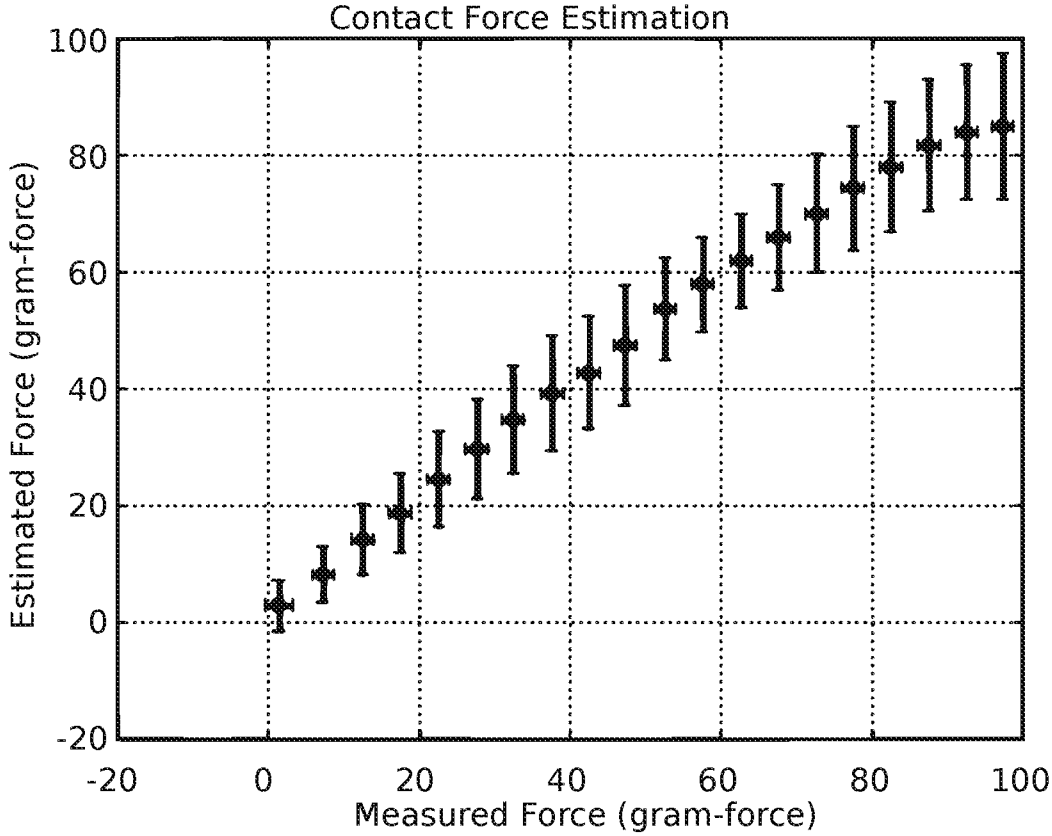

Contact Force Estimation
Estimated Force (gram-force)
Measured Force (gram-force)
100
80
60
40
20
0
-20
-20
0
20
40
60
80
100

FIG. 5

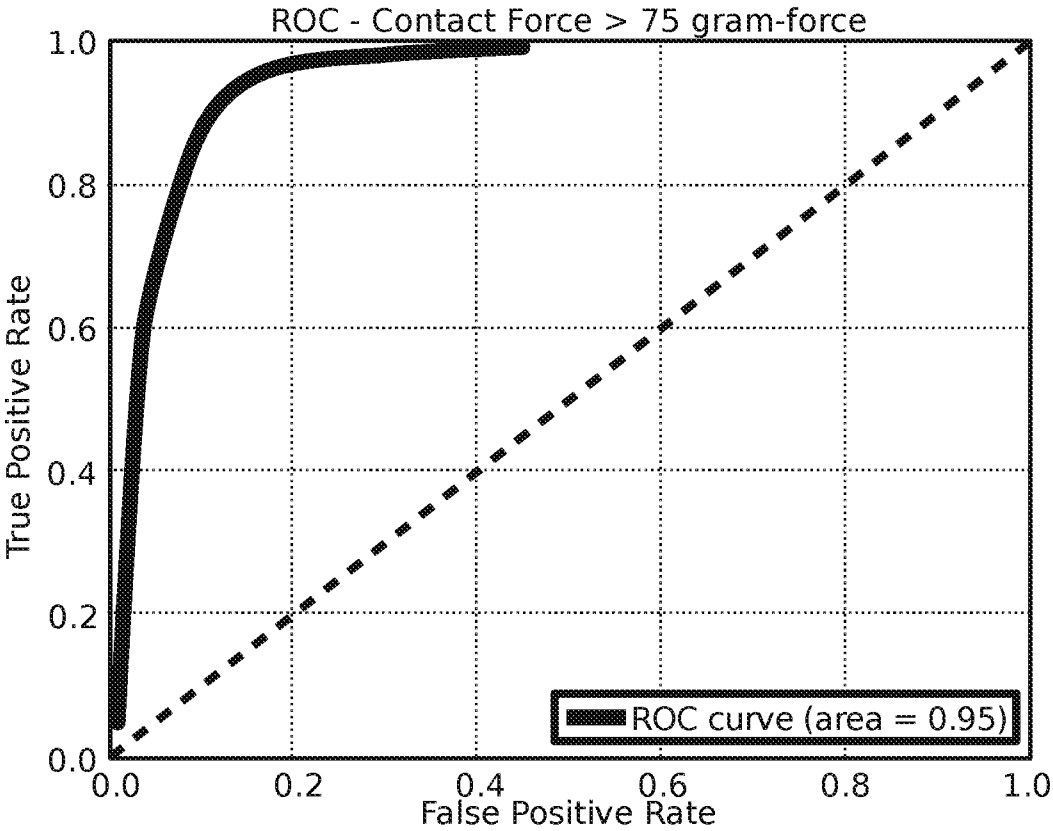

ROC - Contact Force > 75 gram-force
True Positive Rate
False Positive Rate
ROC curve (area = 0.95)
1.0
0.8
0.6
0.4
0.2
0.0
0.0
0.2
0.4
0.6
0.8
1.0

FIG. 6

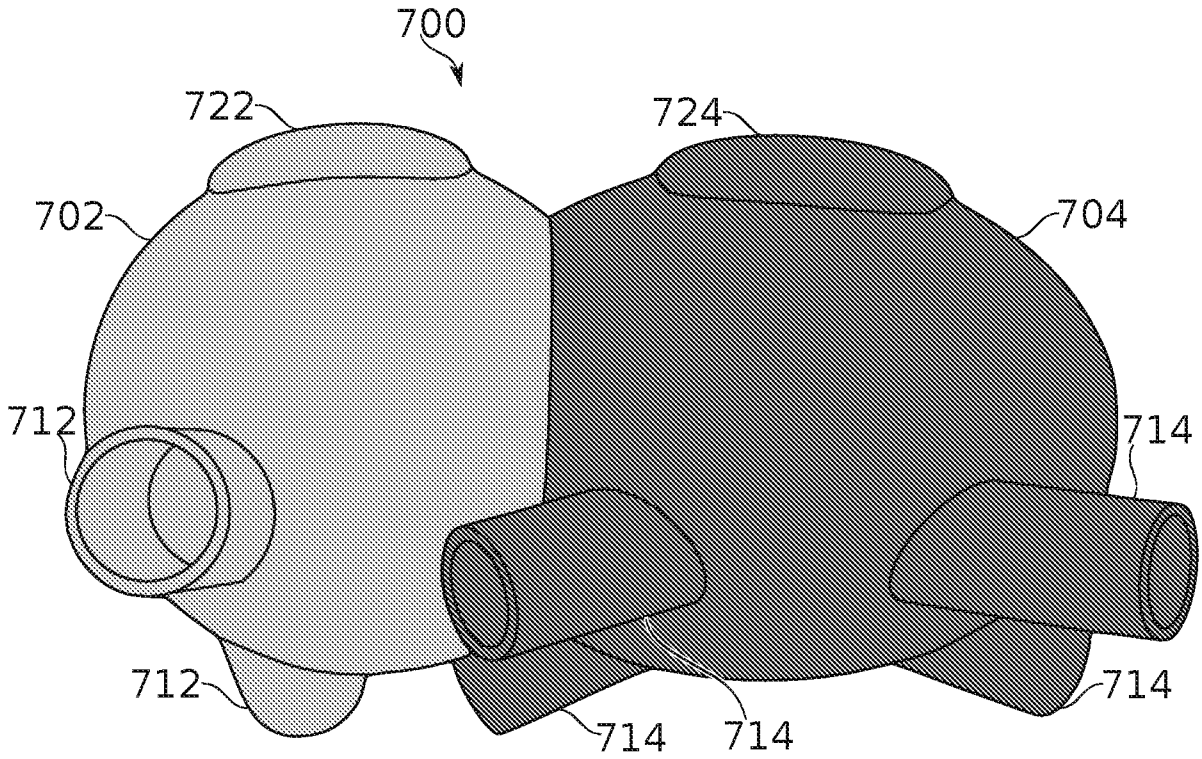

700
722
724
702
704
712
714
712
714
714
714

FIG. 7A

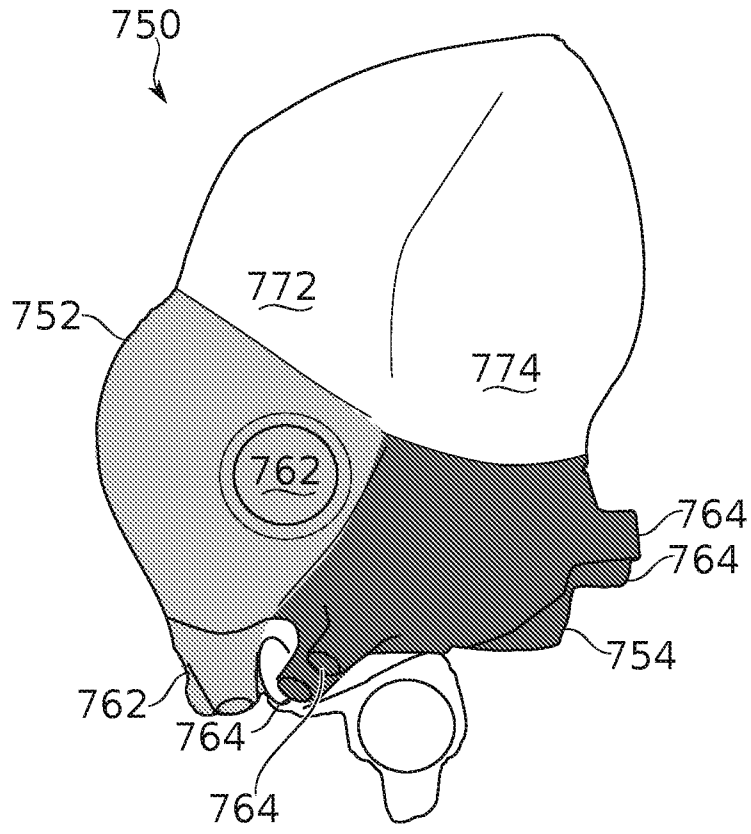

750
772
752
774
762
764
764
754
762
764
764

FIG. 7B

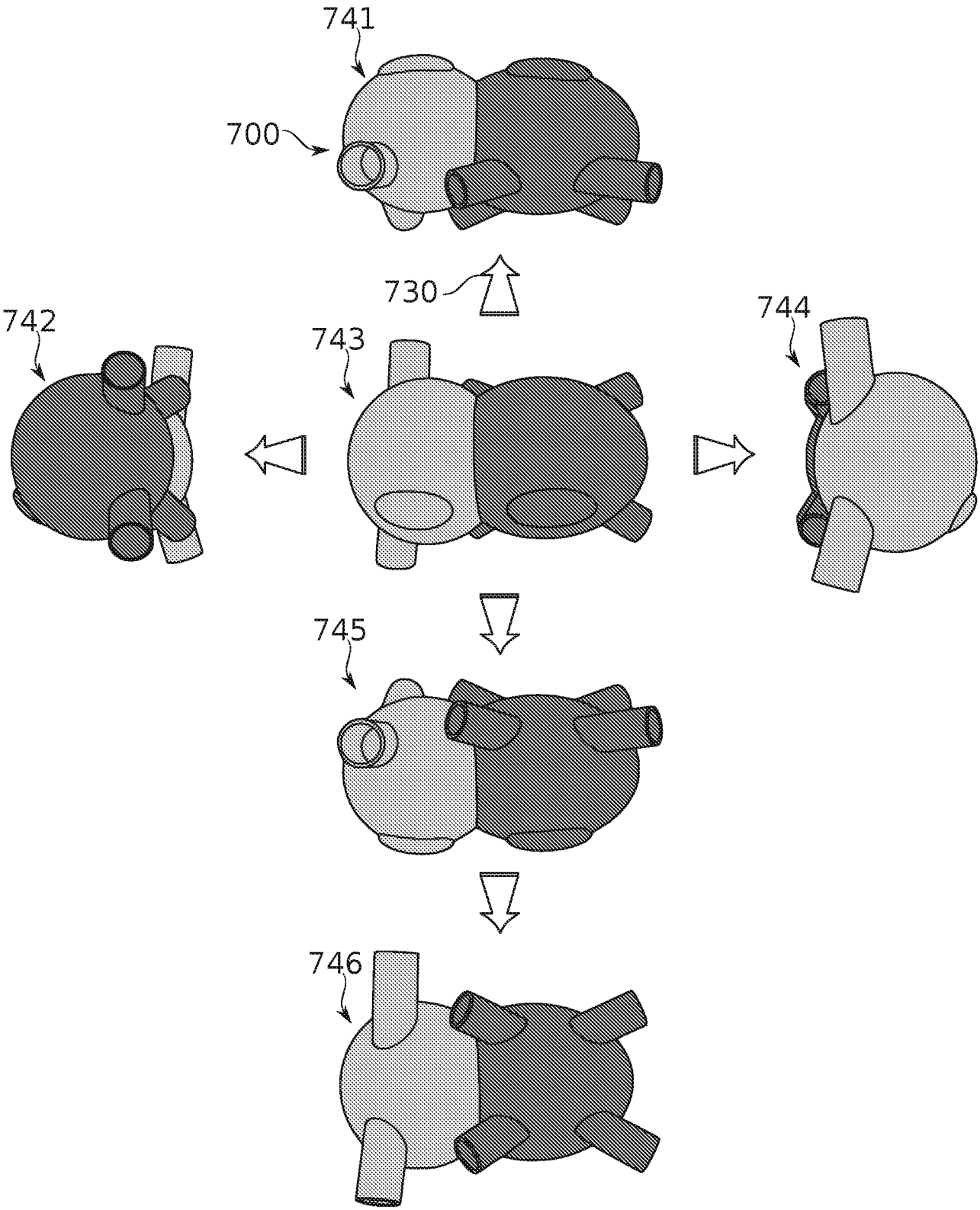


FIG. 7C

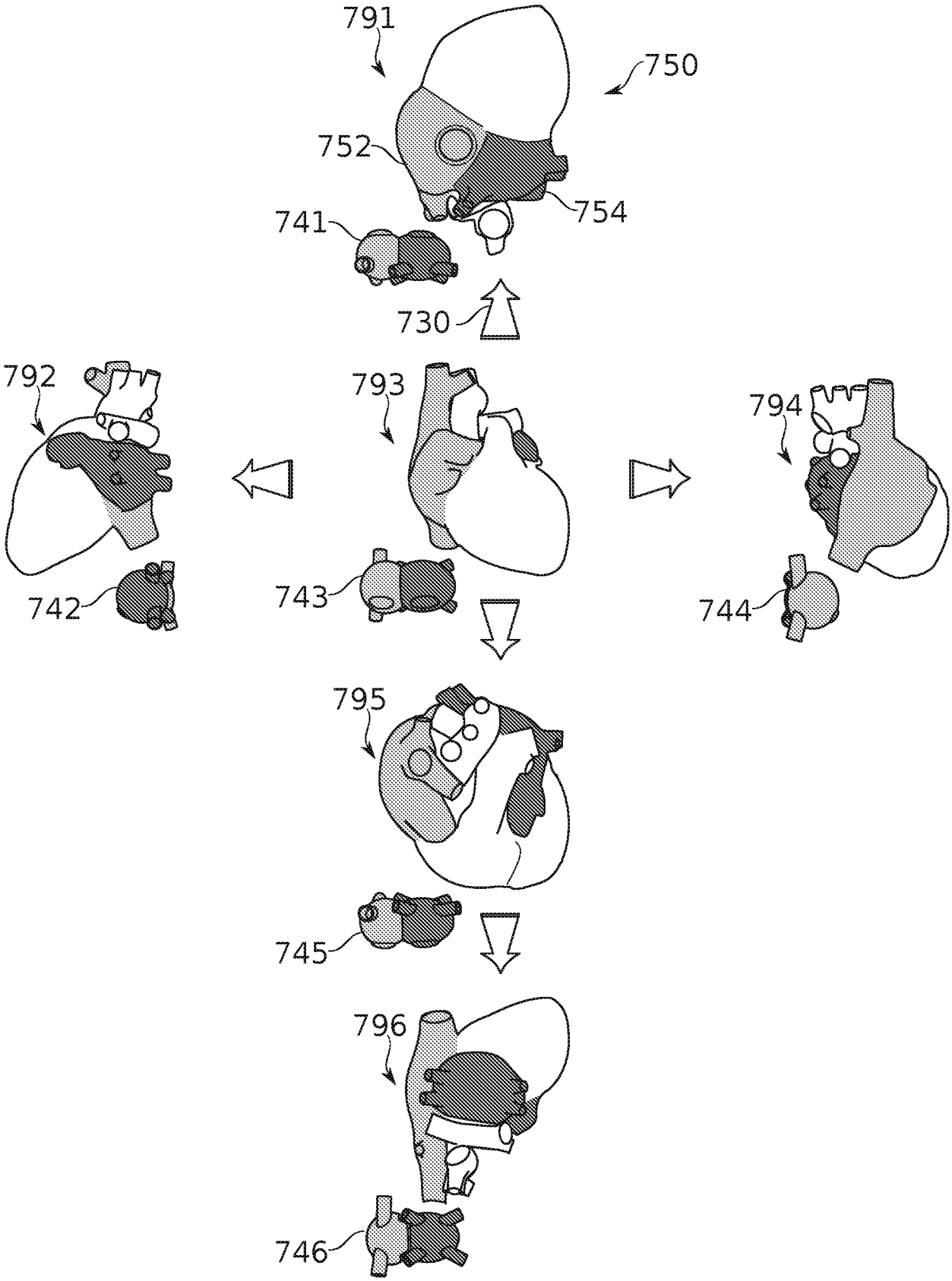


FIG. 7D

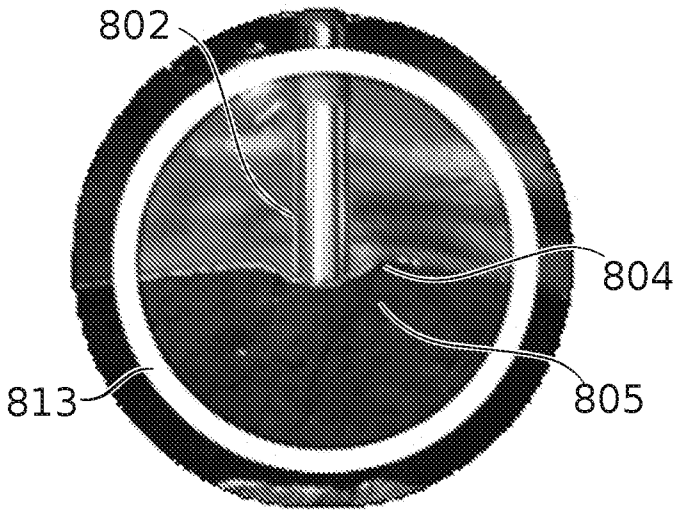


FIG. 8A

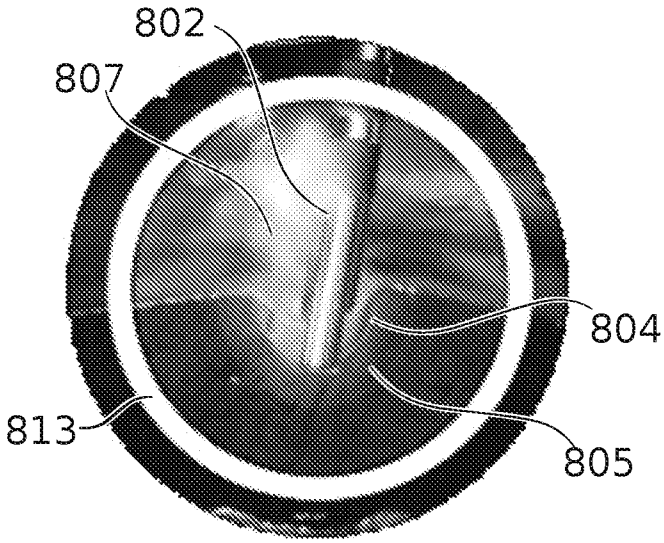


FIG. 8B

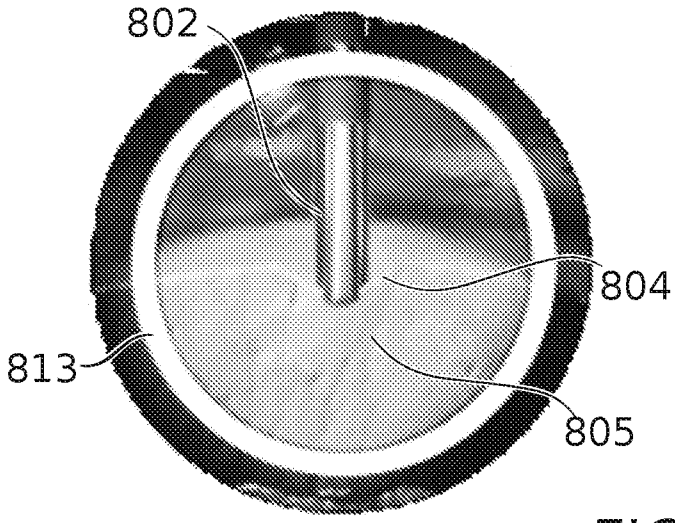


FIG. 8C

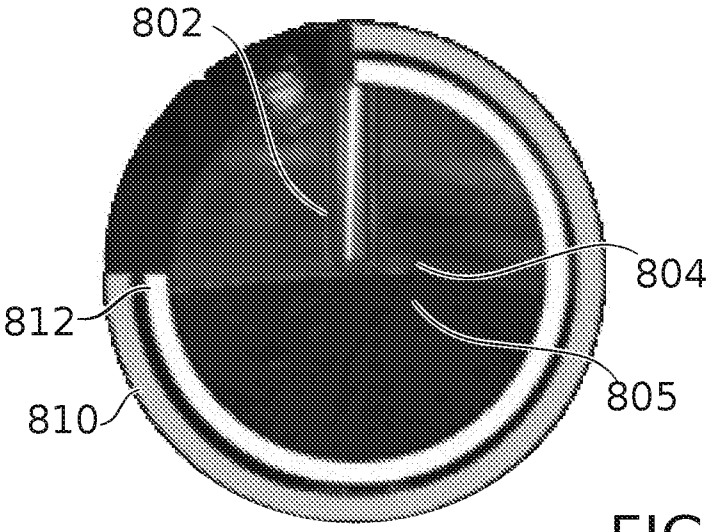


FIG. 8D

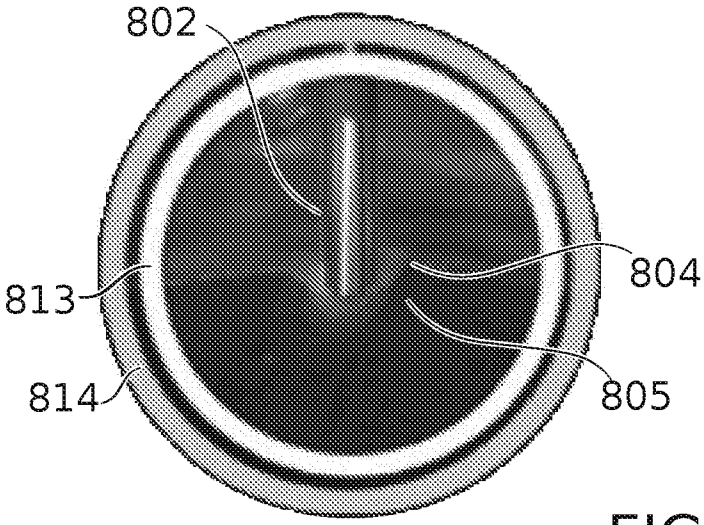


FIG. 8E

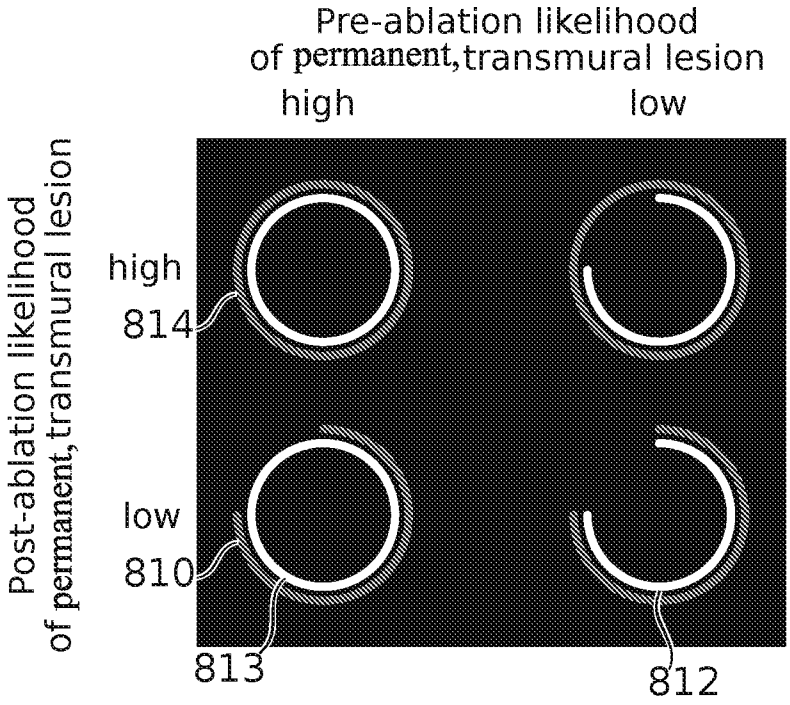

Pre-ablation likelihood
of permanent,transmural lesion
high
low
Post-ablation likelihood
of permanent,transmural lesion
high
814
low
810
813
812

FIG. 9

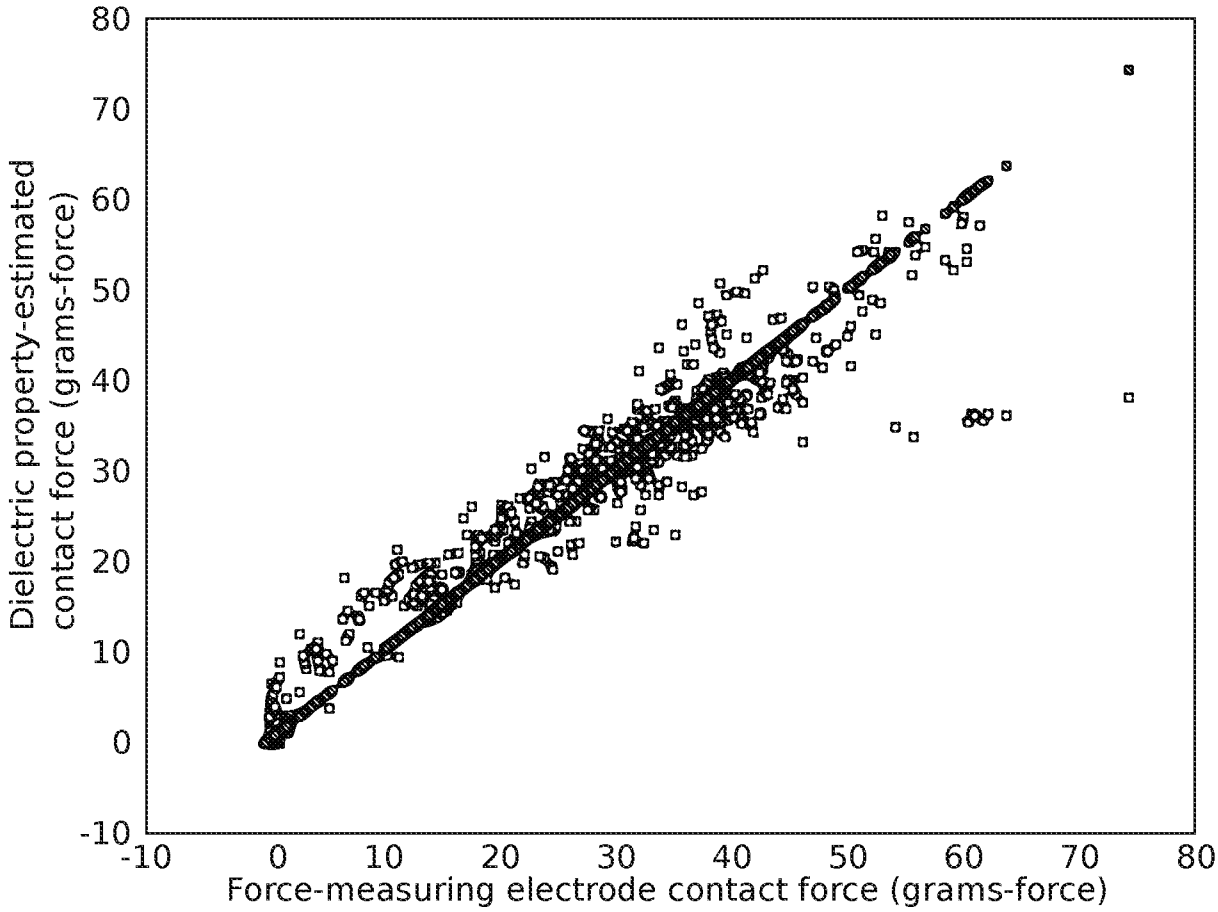

80
70
60
50
40
30
20
10
0
-10
-10
0
10
20
30
40
50
60
70
80
Dielectric property-estimated
contact force (grams-force)
Force-measuring electrode contact force (grams-force)

FIG. 10

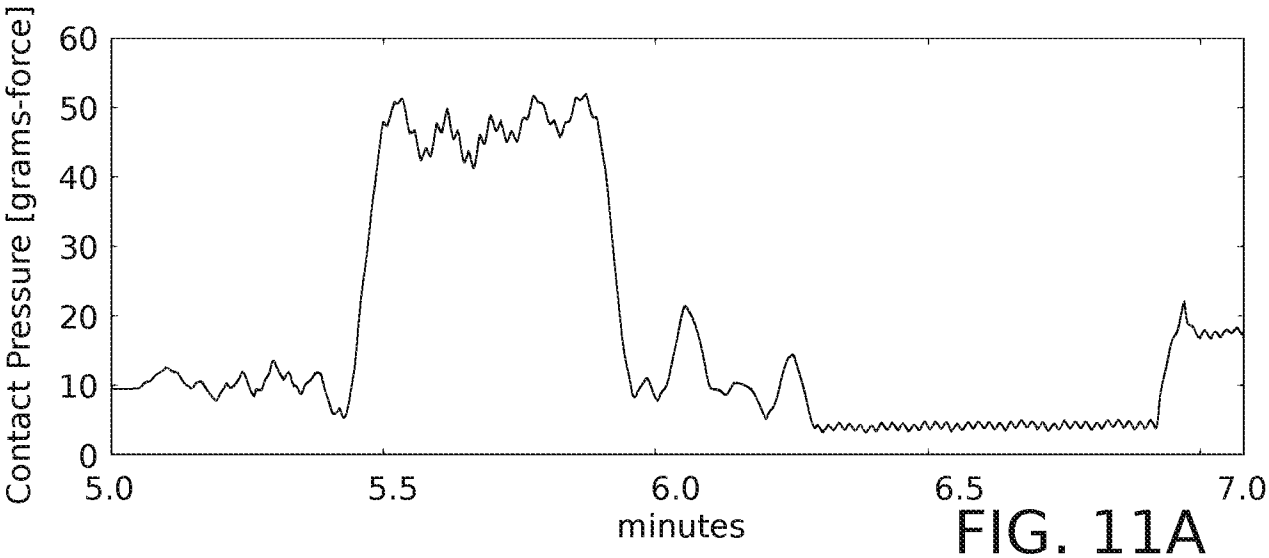


FIG. 11A

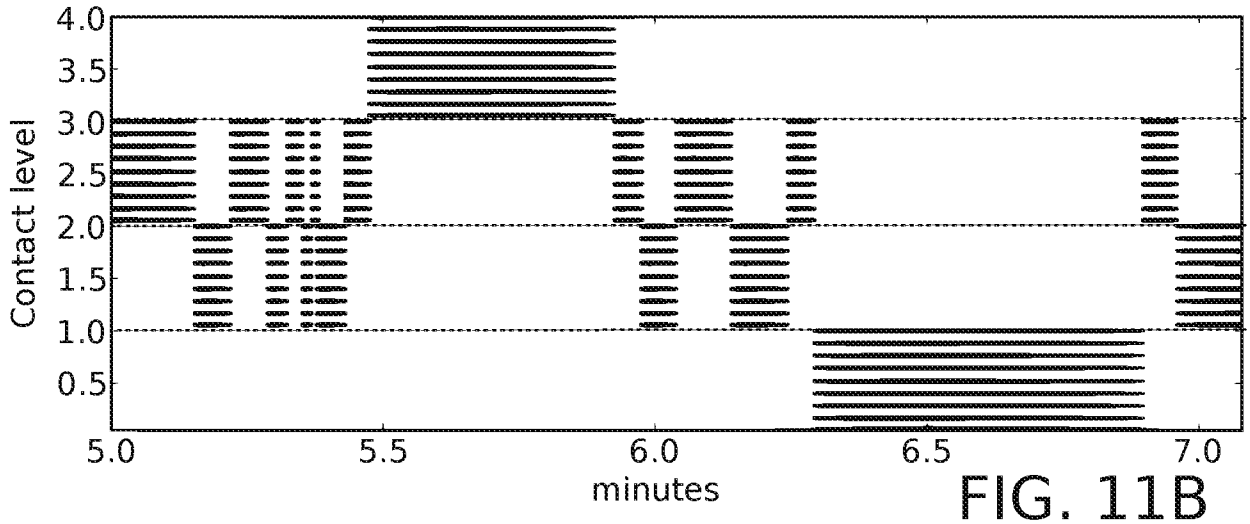


FIG. 11B

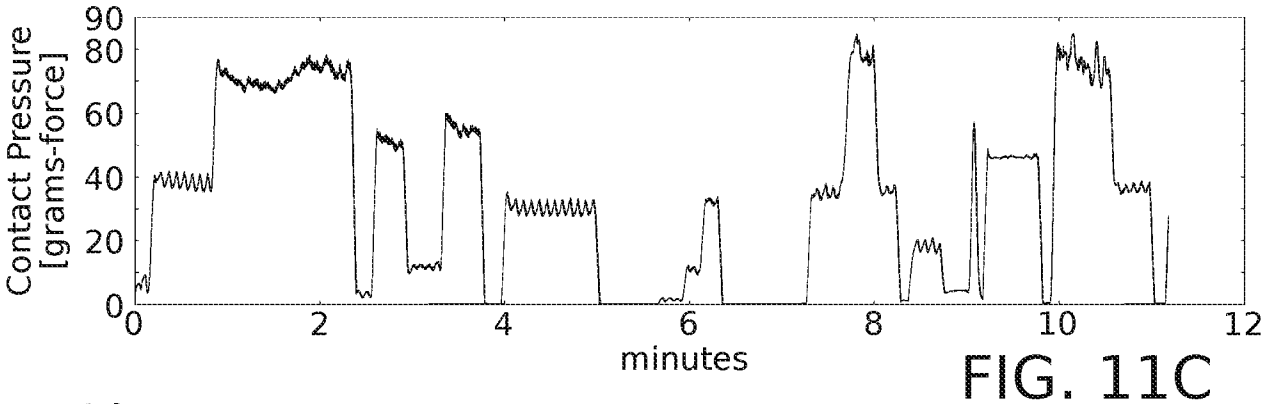


FIG. 11C

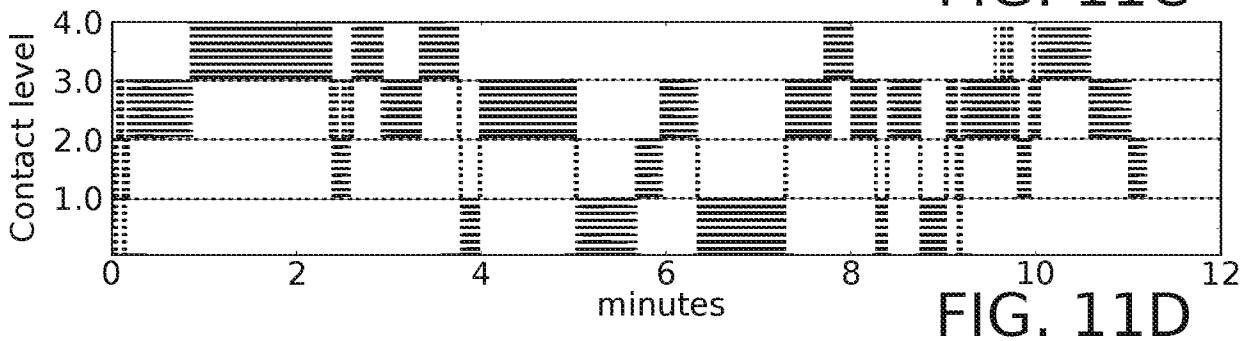


FIG. 11D

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/052686

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61B90/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/274239 A1 (PAUL SAURAV [US] ET AL) 28 October 2010 (2010-10-28) paragraphs [0050] - [0058]; figures 2a,2b	1-9, 15-17, 19,20, 25-33, 40,41
X	US 2003/220636 A1 (BOWMAN BRETT S [US] ET AL) 27 November 2003 (2003-11-27) paragraphs [0031], [0039] - [0044]; figures 14-16	1-9, 14-17, 19-21, 25-33, 40,41

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2016	13/10/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Mayer-Martenson, E

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/052686

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/068931 A1 (WONG YEE CHIN [US] ET AL) 6 June 2002 (2002-06-06) paragraphs [0069] - [0072]; figures 6a,6b -----	1-9, 14-17, 19,20, 25-33, 40,41
X	EP 2 777 584 A1 (COVIDIEN LP [US]) 17 September 2014 (2014-09-17) paragraphs [0042] - [0046]; figure 4 -----	1-9, 14-17, 25-33, 40,41

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2016/052686

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-13, 18, 22-24
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-33, 40, 41

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-33, 40, 41

   Methods and device for dielectric contact sensing

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2. claims: 34-39

   Method of indication of orientation of display of anatomical structure

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2016/052686

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